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PUBLIC ADVOCATE FOR THE CITY OF NEW YORK  
*Solving Problems • Protecting New Yorkers*

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## POLICY

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## Reports

### Section I. Introduction

Nowadays prescription pharmaceuticals are easily accessible over the Internet. According to the federal Food and Drug Administration (FDA), the number of Internet websites selling prescription drugs changes from day to day, and seem to be growing. [1] According to the Office of Criminal Investigations (OCI) and the General Accounting Office (GAO), there are roughly 300 to 400 websites that both dispense and offer prescription services. [2] Half are located internationally. This easy access to prescription pharmaceuticals afforded through the Internet poses a challenge for both regulators as well as policy makers.

Buying drugs online is convenient for consumers. It also offers a sense of privacy that some prefer. Online buying also allows the consumer to shop around various websites, enabling them to look for better deals that may offer cheaper prices. While purchasing prescription drugs over the Internet provides benefits for consumers, its many dangers cannot be discounted. The following are some pitfalls to ordering pharmaceuticals online:

The product may be contaminated and harmful.

The product may be counterfeit and lack the drug's active ingredient.

The product may contain the wrong dose of the drug.

The product may be outdated.

Without adequate screening by a health care professional, the product may not be safe and appropriate for the user.

The consumer may not have access to a health care professional if a serious side effect occurs after taking the product.

Since the consumer is ordering at his or her leisure, the danger of becoming addicted is very high.

The consumer may receive no product at all after sending payment.

The FDA receives reports on only a small fraction of all adverse events caused by drugs due to under reporting. They cannot accurately quantify the number of individuals who have been harmed from drugs purchased over the Internet. However, post

marketing surveillance data collected by the FDA indicates that the illegal sale of drugs over the Internet poses a serious public health risk.

In light of these dangers to consumers, the Office of the Public Advocate conducted an Internet search during the months of December 2002 to March 2003, to discern the amount of ease with which prescription pharmaceuticals can be obtained on-line without a prescription. Even though easy access to any kind of a prescription pharmaceutical without the proper supervision by a healthcare professional is cause for alarm, access to potentially addictive drugs or controlled substances seems even more alarming. A physician's oversight is essential for managing side effects and overdose possibilities. Therefore, our focus was limited to searches on websites offering potentially addictive drugs or controlled substances.

In this report, section one presents an introduction, section two provides the methodology used to conduct the survey, section three discusses the findings from the survey, section four an overview of the regulatory control over Internet sales of pharmaceuticals, and section five offers recommendations. The attached appendix provides the individual websites found to offer controlled prescription drugs.

## Section II. Methodology

The Office of the Public Advocate conducted a search of the worldwide web during the period of December 13, 2002 to March 12, 2003. Even though cyber pharmacies offer numerous varieties of drugs, the main focus of this report was to determine access to prescription pharmaceuticals that were known to have addictive potential.

According to the National Institute on Drug Abuse, the following prescription drugs are known to be commonly abused and potentially addictive:

Opioid Pain Killers – Codeine, Darvon, Vicodin, Demerol;

Central Nervous System Depressants – Valium, Xanax, Halcion;

Stimulants- Ritalin, Dexedrine. [3]

According to the Controlled Substances Act, they are also controlled substances.

Using multiple search engines like Google, Yahoo, Excite, Alta Vista, Hotbot and Lycos, we were able to identify those websites that offered potentially addictive drugs to consumers.

The information we derived from our search has limitations in that we did not attempt to purchase pharmaceuticals from all of the sites. Therefore, we cannot definitively state that all sites will actually deliver the goods as promised.

## Section III. Findings

### Different Categories of Sites

Our Internet search found that several different categories of online pharmacies exist on the web. The first category includes sites with traditional safeguards for prescribing drugs. Examples of these are familiar large drugstore chains, such as, CVS or Walgreens, as well as the local small pharmacies. These sites/pharmacies are licensed to sell prescription drugs by the state in which they operate. Consumers must present a valid doctor's prescription. The pharmacy then verifies the prescription before dispensing the medication. These online pharmacies offer a wide variety of prescription drugs.

The second category includes domestic sites that do not require prescriptions and consumers can easily purchase prescription drugs by filling out an online questionnaire, bypassing any face-to-face interaction with health professionals. These sites claim to have licensed physicians review the on-line questionnaires before dispensing the drugs. However, the accuracy of these statements is certainly circumspect.

Online sites falling under the third category are located outside of the United States, offering drugs without prescriptions. The fourth category includes sites that have two tiers of product lists. In order for the consumer to purchase the second tier of drugs, they have to pay additional membership fees. The drugs offered in the second tier are often controlled substances. It is difficult to determine the location of these sites offering source listings for various drugs.

#### **Location of the Websites**

Our search found twenty-one websites offering access to prescription drugs known to have addictive potential. Two (9.5 percent) of these sites were located domestically, while eleven (52.3 percent) were located internationally. The location of the eight remaining sites (38 percent) could not be determined.

#### **Difficulty of Access**

Of the twenty-one sites found to offer potentially addictive drugs, fourteen (66.6 percent) of these sites offered immediate access, while seven sites (33 percent) charged additional memberships fees in order to access these drugs.

#### **Prescription Requirements**

Because it is illegal to dispense prescriptions drugs without a valid physician's prescription in the United States, many online pharmacies offer their own prescriptions. This is done through filling out online Questionnaires later reviewed by licensed physicians or telephone consultations.

We found that out of the twenty-one sites where potentially addictive prescription drugs were available, none required prior prescriptions. Only three (14.2 percent) of the twenty-one sites required the consumer to fill out either a medical history questionnaire or a telephone consultation before dispensing the drugs. The remaining eighteen sites (85.7 percent) offered these prescription drugs without any form of a medical consultation.

#### **Provision of Customer Service Information**

Conducting business transactions over the Internet has certain risks for the consumer. That is why it is important for on-line businesses to provide the consumer with accurate information, should they need to be directly contacted for trouble shooting purposes. Yet, our survey found that only two ( 9.5 percent) of the sites provided contact information in the form of domestic telephone numbers while the remaining nineteen sites (90.4 percent) only offered e-mail addresses for further contact.

### **Misleading Advertisements**

We also found that cyber pharmacies located within the United States tend to be less blatant in their advertisements due to existing legal regulations surrounding the dispensing of drugs whereas the international sites are less regulated and tend to offer bolder advertisements and dispense drugs with ease.

Many sites take advantage of the confusion surrounding the importation of prescription pharmaceuticals. Eight (38 percent) of the sites were found to inform their customers that it was legal to import pharmaceuticals as long as the amount imported was less than 90 days supply or gave vague references on legality of the issue.

### **Most Commonly Found Potentially Addictive Drugs**

The most commonly found potentially addictive drug was Valium. It was available on eighteen (85.7 percent) of the sites. Whereas, the most difficult to locate was halcion, offered by four (19 percent) of the sites.

## **Section IV: Overview of Regulations and Enforcement**

There is a certain amount of confusion surrounding the legalities of purchasing prescription pharmaceuticals over the Internet. We will begin by clarifying the law as it relates to the dispensing and purchase of pharmaceuticals online.

Both federal and state laws exist to regulate the sale of pharmaceuticals. These regulations also apply to Internet sales as well. There are laws to regulate the sale of drugs as well as to regulate the dispensing of prescriptions.

### **Federal Regulations**

Under the federal Food, Drug, and Cosmetic Act, it is illegal to dispense drugs without a valid prescription issued by a licensed practitioner. [4] Although there is no federal legislation defining how a valid prescription may be obtained, state regulations exist to clarify the matter further.

It is also illegal to import unapproved, misbranded, and adulterated drugs into the U.S., including foreign versions of U.S-approved drugs as well as the re-importation of approved drugs made in the U.S. However, the FDA's personal importation policy allows consumers to import otherwise illegal drugs, under certain circumstances. A letter written by William Hubbard, Associate Commissioner of Policy Planning, and published on the FDA website, states that " Under this policy, FDA permits individuals and their physicians to bring into the

United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the U.S. A patient seeking to import such a product must also provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product." [5]

This has led many to think that importation of drugs without a prescription is legal, as long as they are in small amounts, less than ninety days supply. In fact, nothing can be further from the truth because the policy does not apply to foreign versions of drugs approved in the U.S, particularly when they are being advertised to U.S consumers. Simply put, it is illegal to import drugs into the United States. Furthermore, the Controlled Substances Act of 1970 prohibits the importation of controlled substances into the United States.

### **Federal Enforcement**

The federal enforcement responsibility for Internet prescription pharmaceutical sales falls under the purview of the following governmental agencies:

Food and Drug Administration (FDA);

United States Customs Service;

Drug Enforcement Agency;

United States Postal Services

### **Department of Justice.[6]**

The FDA regulates safety, effectiveness and manufacturing of pharmaceutical drugs. Domestic sites selling prescription drugs without a valid prescription are doing so illegally. When sites are found to be dispensing pharmaceuticals without a valid prescription, the FDA works in collaboration with the Department of Justice to take criminal or civil enforcement actions.

However, with the worldwide web reaching millions of people each second, oversight by regulatory as well as law enforcement agencies is a daunting task. Foreign web sites are especially challenging for U.S regulators because of the jurisdictional issues. While cyber-pharmacies located in the United States are bound by the laws of this country and the FDA can enforce infringements of the FD&C Act, the agency would have a difficult job enforcing the Act against foreign sellers. They would need the cooperation of their counterparts in the countries where these international sites are located.

The U.S Postal service is required to send all international mail to the U.S Customs Service. This is where the Customs Department comes into play by stopping imported drugs at a U.S port-of-entry. Customs officials identify parcels that may violate the FD & C Act. The FDA then issues a notice to the addressee, providing them with an opportunity to respond to the violation. If no answer is forthcoming, the parcel is sent

back to the exporter. In the case of controlled substances, the enforcement is handled by the DEA who seize the suspected shipments.

According to the U.S Customs Service, seizures of parcels containing controlled substances increased by 450 percent in FY 1999, primarily due to Internet sale of drugs. The FDA estimates that approximately 2 million parcels containing FDA-regulated pharmaceuticals enter the U.S each year. It is troubling to note that the FDA detains and refuses few mail imports for personal use, causing tens of thousands of parcels that may violate the FD & C Act to reach their destinations.[7]

### **State Regulations**

State governments also have their own legislations and regulations surrounding the dispensing of prescriptions for pharmaceuticals as well as for the dispensing of the pharmaceuticals themselves. Pharmacies, pharmacists and physicians are registered and licensed by their respective state pharmacy and medical boards. The State Medical Practice Act defines the practice of medicine and what constitutes unlawful practice of medicine in the state. Certain states have enacted legislation stating that prescriptions issued on the basis of an online questionnaire do not meet the accepted standard of care and are considered outside the bounds of professional medical conduct.

According to information received from the Federation of State Medical Boards, nine states are known to have passed legislation requiring physical examinations prior to prescribing drugs. These states include (Arizona, CA, FL, Kentucky, Missouri, Nevada, Ohio, Virginia and Washington).

For example, Nevada passed a 2001 legislation barring physicians associated with Internet pharmacies from dispensing prescriptions without conducting a physical examination within the past six months. Due to this law, many sites are now refusing to ship their products to Nevada. In fact, two out of the twenty-four sites found to be offering potentially addictive drugs specifically state that they would not ship to residents of Nevada.

In New York State, State Senator Kemp Hannon sponsored a bill in 1999 amending the Public Health Law and Education law by prohibiting the dispensing of controlled substances through the Internet. The bill was never passed. Although non-resident pharmacies must now register with the New York State Board of Pharmacy and provide a toll-free number for customers to contact a pharmacist who has access to the patient's records, the issue of prescribing drugs over the internet through on-line questionnaires still needs to be addressed.[8]

### **State Enforcement**

The state entities responsible for enforcement responsibilities include the state pharmacy and medical boards as well as the state Attorney General's Offices. Twenty-nine states have taken some enforcement action against online pharmacies as well as physicians prescribing drugs over the Internet. These states include (Arizona, California, Ohio, Texas, Washington, Wisconsin, and Wyoming). In March of 2003, the Florida

Pharmacy Board levied a \$48,000 fine against an online pharmacy for filling prescriptions that were not valid. The New Jersey Attorney General filed suit against two on-line pharmacies for illegally selling drugs over the Internet in 2001. In May of 2002, the Manhattan District Attorney's Office filed charges against five companies selling counterfeit versions of Viagra from India and China.

While enforcement actions can be taken against domestic sites, state enforcement agencies also share the difficulties federal agencies face when dealing with illegal international sites. It is even more difficult when the locations of these cyber pharmacies cannot be determined, as we found in our earlier findings.

### **Industry Activity**

In 1999, the National Association of Boards of Pharmacy developed the Verified Internet Pharmacy Practice Sites, in response to public concern over the safety of pharmacy practices on the Internet. The program establishes certification requirements that show a pharmacy complies with the licensing and inspection requirements of the state. An online pharmacy with the VIPP seal represents sites that have met criteria related to authenticity of prescription orders. To date, eight online pharmacies are certified by NABP.

### **Section V. Conclusions and Recommendation**

Our survey has determined that potentially addictive prescription pharmaceuticals are easily accessible over the Internet. It is deeply troubling to find that these kinds of drugs are just a mouse click away. To address this serious public health issue, the Public Advocate recommends the following:

#### **Stricter enforcement efforts by FDA, U.S Customs and the DEA**

The relative ease with which potentially addictive pharmaceuticals can be accessed online underscores the urgent need for greater regulatory enforcement. The FDA should increase active review of international as well as domestic sites that are illegally dispensing prescription pharmaceuticals. While taking into consideration the enormous difficulties and limitations the FDA, Customs and the DEA have in enforcing existing laws on the importation of drugs, they must be more diligent in their enforcement efforts as well as improve and streamline their regulatory process. U.S regulatory agencies should also increase collaboration with foreign regulatory bodies to investigate and take actions against website operators who are illegally shipping drugs to other countries.

#### **Increase Public Education on the Dangers of Purchasing Pharmaceuticals Online**

Greater efforts must be taken to raise public awareness on the dangers of buying prescription pharmaceuticals online. This can be accomplished through public education campaigns. The FDA already publishes guidelines on this topic. They must work to enhance the dissemination of this important tool.

Encourage the New York State Legislature to Enact Legislation  
Addressing Online Dispensing of Prescriptions

New York State should enact legislation similar to the ones in  
states like Nevada, prohibiting the dispensing of prescriptions  
over the Internet without a proper face-to-face physical  
examination.

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