

The Marketing of Opioid Medications Without Prescription Over the Internet

Robert F. Forman and Lauren G. Block

No-prescription Web sites are online pharmacies that supply controlled substances without a valid prescription. The authors present a comprehensive investigation and content analysis of no-prescription Web sites, including a review of the legal environment, an in-depth critique of policy and interventions, and suggestions to help monitor and shut down these illegal sites.

With more than one billion Internet users worldwide and 200 million in the United States, the Internet is a vital medium for communication, entertainment, and commerce (Clickz Network Statistics 2005). The Pew Internet & American Life Project reports that 100% of U.S. college students, 78% of 12- to 17-year-olds, and 67% of all adult Americans go online at least monthly (Lenhart, Madden, and Hitlin 2005); similarly, two-thirds of Internet users have made purchases online, and the same number (66%) use the Internet to look for health and medical information (Pew Internet & American Life Project 2005). Although the Internet offers many benefits to the public, it also presents unique challenges (Sappington and Silk 2003).

Approximately half of all American adults take a prescription medication regularly, and one in four has used the Internet to learn about prescription medications (Fox 2004). Although the Internet is a popular source of information about medications, the majority of Americans have greater confidence in their local pharmacy than in Internet-based pharmacies, and only approximately 4% report having purchased medications online (Fox 2004). Online pharmacies may be particularly appealing to disabled or otherwise homebound consumers, people who need 24-hour access, and those seeking privacy when making purchases (Hubbard 2004).

In addition to the many legitimate online pharmacies that operate in accordance with local and federal laws, a great number of online operations have appeared that offer to sell controlled substances, such as opioid medications, without regard for the prevailing national laws. The Controlled Substances Act (21 U.S.C.S. § 801) prohibits the sale of Schedule I drugs, such as marijuana, heroin, psilocybin, crack cocaine, and ecstasy, and regulates access to Schedule II–V drugs, including analgesics, sedatives, stimulants, and steroids, by requiring a valid prescription from an appropri-

ately licensed health care professional. Many countries have drug policies that differ from those of the United States or have similar laws but less enforcement. People who want to sell drugs, such as opioid medications, to customers in the United States can do so through Web sites that exploit the virtual nature of the Internet and the challenges that virtuality present to law enforcement and regulation (Center on Addiction Substance Abuse 2006; Forman 2003, 2006; Forman et al. 2006).

A “no-prescription Web site” (NPW) offers to sell controlled substances without a valid prescription, disregarding U.S. federal and state laws. The fluidity and semireality of cyberspace are ideally suited to illicit drug transactions, creating a complex challenge for law enforcement, policy makers, and the general public (Attorney General’s Office 2000; The White House 1999). For example, an NPW can be physically located on a computer in Uzbekistan, can be registered to a business address in Mexico, can ship its drugs from Pakistan, and can deposit payments to a Cayman Island bank, while the owner resides in Miami. Importantly, all links in this online enterprise can be quickly dismantled and resurrected under a new set of virtual identities. Moreover, although the delivery of controlled substances, such as opioid medications, without a prescription is illegal in the United States, other countries permit the sale of these controlled substances without prescription. Nonetheless, although U.S. laws prohibit these Web sites from making sales in the United States, enforcement of the laws is challenging.

In this article, we present the first comprehensive analysis of NPWs, including a review of the legal environment and an in-depth critique of policy and interventions. Previous articles by the first author have documented the problem and the existence of the NPW database as a starting point in tracking such NPWs. However, the current article goes beyond these prior publications by adding a content analysis of NPWs and providing a wide range of policy recommendations. Importantly, before this article, there has been no systematic analysis of the content and particular features of typical NPWs beyond mere qualitative summaries. We present the results of the first systematic content analysis of NPWs and suggest how these results can help guide policy for monitoring and shutting down these illegal sites. Although a wide range of controlled substances is offered

Robert F. Forman is a Clinical Scientist at Alkermes (e-mail: robert.forman@alkermes.com). *Lauren G. Block* is Professor of Marketing, Zicklin School of Business, Baruch College, City University of New York (e-mail: Lauren_Block@baruch.cuny.edu). The authors gratefully acknowledge Stephanie Catella and Keith Wilcox for their data and coding assistance and Dr. George E. Woody for his helpful comments on previous drafts of the article.

for sale online, including stimulants, steroids, sedatives, hallucinogens, and marijuana, we limit our focus to opioid medications because several national surveys have reported that abuse of this class of substances has increased most rapidly in the past five years (Department of Health and Human Services 2003; Johnston et al. 2005; Substance Abuse & Mental Health Services Administration 2003a, b). In addition, misuse of opioid medications can lead to serious health consequences, including fatal overdose. Although the reasons for increased abuse of opioid medications are unknown, the leadership of the National Institute on Drug Abuse (Volkow 2004), the White House Office of National Drug Control Policy (2004), and the International Narcotics Control Board (2005; hereinafter INCB) have all cited the emergence of “rogue online pharmacies” as a critical contributing factor.

Legal Background

Reports from law enforcement agencies have documented the illicit sale of controlled substances online. The earliest report we are aware of was from the U.S. Justice Department, issued on September 30, 1999, by Ivan Fong, Deputy Associate Attorney General, before the Subcommittee on Oversight and Investigations Committee on Commerce, United States House of Representatives. In his testimony, Mr. Fong reported (see Section 8 of the statement) that “online pharmacies allow consumers to purchase prescription drugs without any pretense of a prescription.” He noted that such pharmacies may originate in countries in which quality standards do not meet Food and Drug Administration (FDA) requirements for approval in the United States and in which such an activity is legal, thus making it complicated to prohibit these firms.

“The Electronic Frontier” Report

One week later, on August 6, 1999, the White House issued Executive Order 13133, creating the “Working Group on Unlawful Conduct on the Internet” headed by the U.S. Attorney General and composed of the leadership from 11 federal agencies, including the Federal Bureau of Investigation; the Drug Enforcement Administration (DEA); the FDA; the Federal Trade Commission; the Bureau of Alcohol, Tobacco, Firearms, and Explosives; the Treasury Department; the Department of Commerce; the Department of Education; and several others. Executive Order 13133 charged the special panel with the task of determining the adequacy of current laws and enforcement practices while making clear the administration’s intent to provide “support for industry self-regulation where possible, technology-neutral laws and regulations, and an appreciation of the [I]nternet as an important medium both domestically and internationally for commerce and free speech” (§ b.1.).

In March 2000, “The Electronic Frontier: The Challenge of Unlawful Conduct Involving the Use of the Internet: A Report of the President’s Working Group on Unlawful Conduct on the Internet” was released (Attorney General’s Office, U.S. Justice Department 2000). In this report, several challenges that the Internet presented to law enforcement were identified, including the inadequacy of international cooperation among law enforcement agencies and the

subsequent shielding of criminal operations. In addition, the report highlighted the rapid development in advanced information technologies (i.e., encrypted e-mail) and the challenges that law enforcement faced in maintaining adequate technical capabilities.

Despite recognition of these challenges, “The Electronic Frontier” concluded that current policies and regulations to control illicit Internet drug sales were adequate: “Apart from new legislative efforts to require online pharmacies to make certain disclosures or to obtain appropriate certifications, existing substantive federal law (for now at least) appears to be adequate” (Attorney General’s Office, U.S. Justice Department 2000, p. 25).

DEA Guidance Document

Less than a year after the release of “The Electronic Frontier,” the DEA (2001) issued “Dispensing and Purchasing Controlled Substances Over the Internet” to provide guidance in applying existing laws governing the sale of controlled substances to online drug sales. This notice stated that the issuance of prescriptions for controlled substances requires that four conditions be met: (1) a patient has a medical complaint; (2) a medical history has been taken; (3) a physical examination has been performed; and (4) some logical connection exists among the medical complaint, the medical history, the physical examination, and the drug prescribed (p. 21183). Consequently, online questionnaires and/or telephone evaluations are inadequate bases for a legal prescription of controlled medications. These requirements are intended to ensure that patients will receive an adequate medical evaluation before these addictive and potentially harmful medications are prescribed, which would ultimately serve the public interest for safety and professional guidance.

FDA Initiatives

Just before the release of “The Electronic Frontier” report, the FDA (2000) began sending electronic “cyber letters” to operators of foreign Web sites that offered to sell drugs illegally over the Internet to U.S. consumers. These cyber letters provided the Web site operators with the relevant statutes and advised that their practices were potentially harmful to U.S. citizens. Hard copies of the cyber letters were also sent, and copies were forwarded to U.S. Customs and local regulatory representatives for the host countries in which the Web sites operated. In addition to the cyber letter initiatives, the FDA also issued policy statements and public notices about the risks associated with purchasing medications online (FDA 2003a; Henney 2000; Hubbard 2003). Finally, in conjunction with U.S. Customs, the FDA participated in several investigations of illicit prescription drug sales that originated overseas (FDA 2003b).

The FDA’s Office of Criminal Investigations maintains ongoing liaisons with numerous government agencies in Canada, the United Kingdom, Spain, Germany, Belgium, the Netherlands, Ireland, Brazil, Singapore, and others. Likewise, the DEA and the U.S. Office of Homeland Security, particularly the U.S. Customs Narcotics Division, work together to investigate and interdict illicit narcotics headed for the United States. However, to address the problem effectively of NPWs shipping drugs from overseas, the

United States government must work with foreign governments that are willing and able to cooperate in its enforcement efforts.

International Coordination

In addition to cooperative efforts with individual countries, the INCB is the primary international organization dedicated to addressing the international drug diversion problem. The INCB's (2005, p. 29) report noted that "[n]arcotic drugs and psychotropic substances are increasingly being advertised and illicitly sold without required prescriptions by Internet pharmacies; the pharmacies are thus not only operating in contravention of international and national legislation but also subjecting customers to serious health risks." The INCB goes on to note (p. 29) that "the Internet has been acting as a substitute for trafficking channels that have been successfully closed." The INCB is a monitoring and coordinating organization without enforcement capabilities.

Prescription Opioids Online

Legitimate online pharmacies (e.g., www.drugstore.com, www.caremark.com) provide convenience and efficiency to consumers while complying with the regulations of the states in which they dispense medications; in particular, legitimate online pharmacies require a valid prescription from the consumer's physician. However, hundreds of NPWs sell prescription medications solely on the basis of an online questionnaire, a telephone interview, or a simple online order without any interaction with a physician or other licensed health care professional. The American Medical Association (Policy H-120.949 and H-120.956, see http://www.ama-assn.org/apps/pf_new/pf_online) and the National Association of Boards of Pharmacy (2003) have issued policy statements that support the Internet as a medium for processing legitimate prescriptions while simultaneously recognizing that Web sites selling prescription medications without appropriate medical guidance are a threat to public health.

To address what these professional organizations and federal agencies perceived as a growing problem, a coalition was formed to create the Verified Internet Pharmacy Practice Sites (VIPPS) program in the spring of 1999 (National Association of Boards of Pharmacy 2003). Online pharmacies that meet the VIPPS quality standards are allowed to place the VIPPS-certified logo on their Web site. The VIPPS certification program applies only to Web sites that are hosted in the United States and a few other cooperating countries. Moreover, because the National Association of Boards of Pharmacy can influence only pharmacies that belong to its network, it is unlikely to influence NPWs that already disregard the Controlled Substances Act. Indeed, the National Association of Boards of Pharmacy has few options if an NPW were to paste the VIPPS logo onto its site, falsely claiming certification.

Availability of NPWs

Search engines, such as Google and Yahoo, make it relatively easy to find NPWs (Forman 2003; Forman et al. 2006). In more than 50 Internet-monitoring studies in which

search terms such as "no prescription codeine" and "no prescription Vicodin" were used, more than 50% of the links returned for these terms led to Web sites that offered to sell opioid medications without a prescription (Forman et al. 2006). In Forman and colleagues' (2006) studies, a simple search on the term "Vicodin" typically yielded 40%–50% NPW links. When the search prefix "no prescription" was added to the drug term, the proportion of NPWs obtained was consistently increased to 60%–80%. There are two general categories of NPWs: Retail NPWs offer to sell opioid medications directly without prescription, and portal NPWs provide multiple links to retail NPWs. The majority of the NPWs obtained in monitoring studies conducted since 2003 were classified as portals.

As Figure 1 illustrates, the proportion of links categorized as NPWs for the term "no prescription codeine" was somewhat stable over the course of ten monitoring studies, ranging from a low of 53% of links categorized as NPWs to a high of 88%. The percentage registered outside the United States was also relatively stable; most foreign NPWs were registered to Canada and the United Kingdom. It is worth noting that in June 2004, a new trend was identified in which NPWs registered to countries of the former Soviet Union (e.g., Russia, Belarus, Ukraine) emerged. The emergence of NPWs hosted in Eastern European countries is important because of their geographic proximity to opium-producing countries (e.g., Afghanistan, Pakistan) and the limited law enforcement resources there. It is possible that opium harvested in Afghanistan could be converted to generic opioid medications and sold online cheaply, while still generating enormous profits.

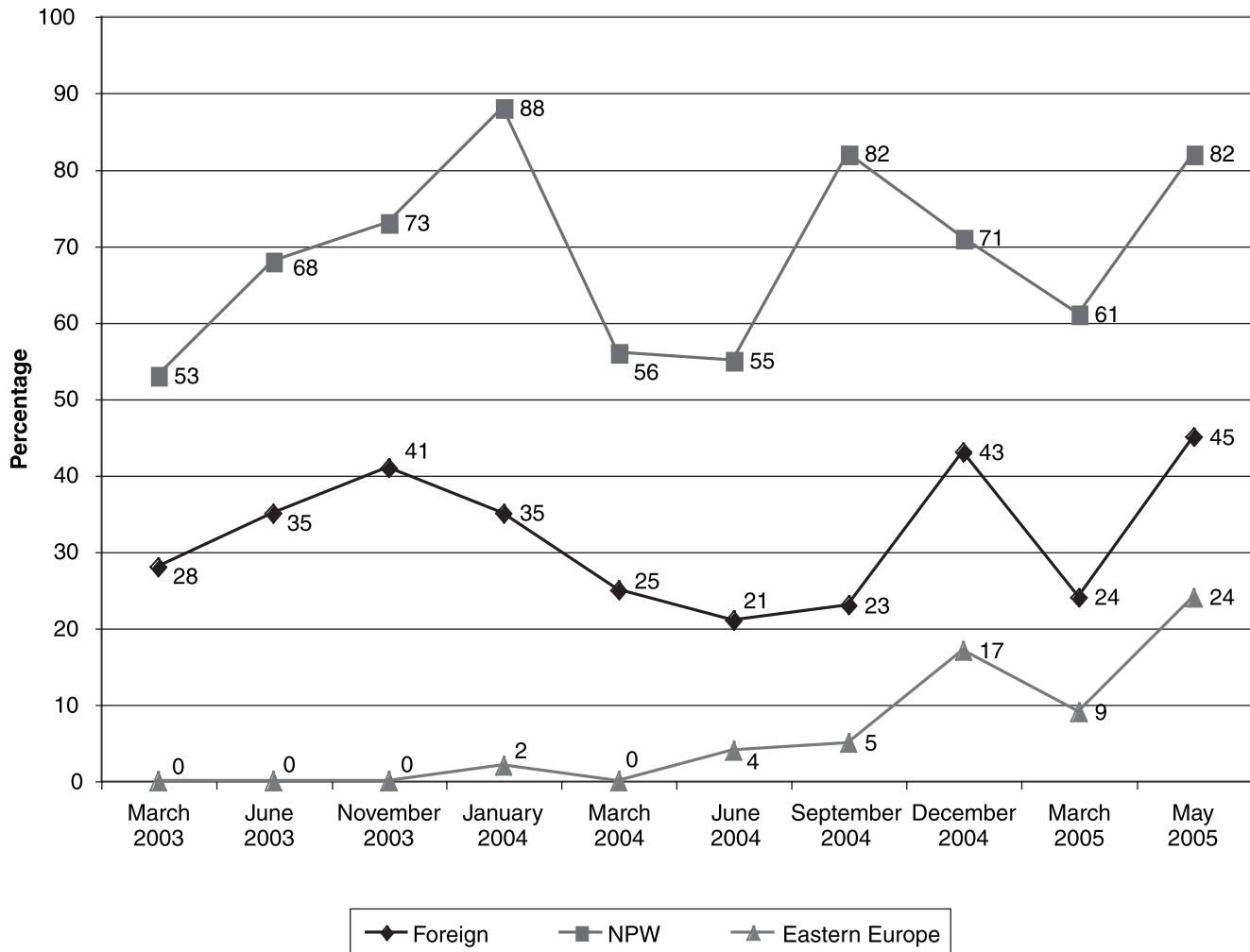
NPWs on Google Versus Yahoo

The NPW-monitoring studies we reported previously were conducted using Google. In one systematic comparison using the term "no prescription Vicodin" in both Google and Yahoo, more NPWs were obtained in Yahoo (93) than in Google (76; Forman et al. 2006). This was only a single intersearch engine comparison, and the reliability of this finding is unknown. Nonetheless, the results suggest that the responses obtained in Google are not unique and may even be an underestimation of what may be found using other search engines. Although both search engines promote "sponsored links" at the top and/or on the right-hand margin of search returns, the policies of both leading search engines claim that advertisements of controlled substances without prescription is prohibited.

Digital Darwinism

Search engines determine which Web sites will receive top ranking on the basis of proprietary algorithms, which the search engines frequently refine to optimize the relevance of search results. Because people conducting searches view the first 10–20 links, Web sites in these top ranked positions receive the most referrals and, in the case of NPWs, potentially the most customers.

To assess the relative availability of NPWs versus Web sites that offered addiction health information (e.g., WebMD), during the first two weeks of August 2004, Forman and colleagues (2006) conducted 27 Google searches using a wide variety of opioid search terms. The procedures

Figure 1. Proportion of NPWs Identified in Google Using the Search Term “No Prescription Codeine”

employed in these 27 searches were identical to those we described previously, except only the first 20 links were examined for each drug search term. Search terms included (1) generic opioid medication names (e.g., “hydrocodone”) and (2) opioid medication brand names (“Vicodin”). For each generic and brand name opioid medication, additional searches were conducted using the prefix “no prescription” (e.g., “no prescription hydrocodone”). The resulting Web sites were categorized as before, except that the coding category “addiction health information” (e.g., the National Institute on Drug Abuse’s Web site: <http://www.nida.nih.gov>) was added. As Figure 2 reveals, two search terms, “no prescription Vicodin” and “no prescription hydrocodone,” yielded 80%–90% NPWs and no links to addiction health information Web sites. Conversely, several opioid medications, including fentanyl, Duragesic, buprenorphine, and Subutex—with and without the “no prescription” prefix—yielded a majority of addiction health information Web sites and few or no NPWs. These differences in NPW rates roughly parallel rates of abuse reported in other studies

(Department of Health and Human Services 2003; Johnston et al. 2005; Substance Abuse & Mental Health Services Administration 2003a, b).

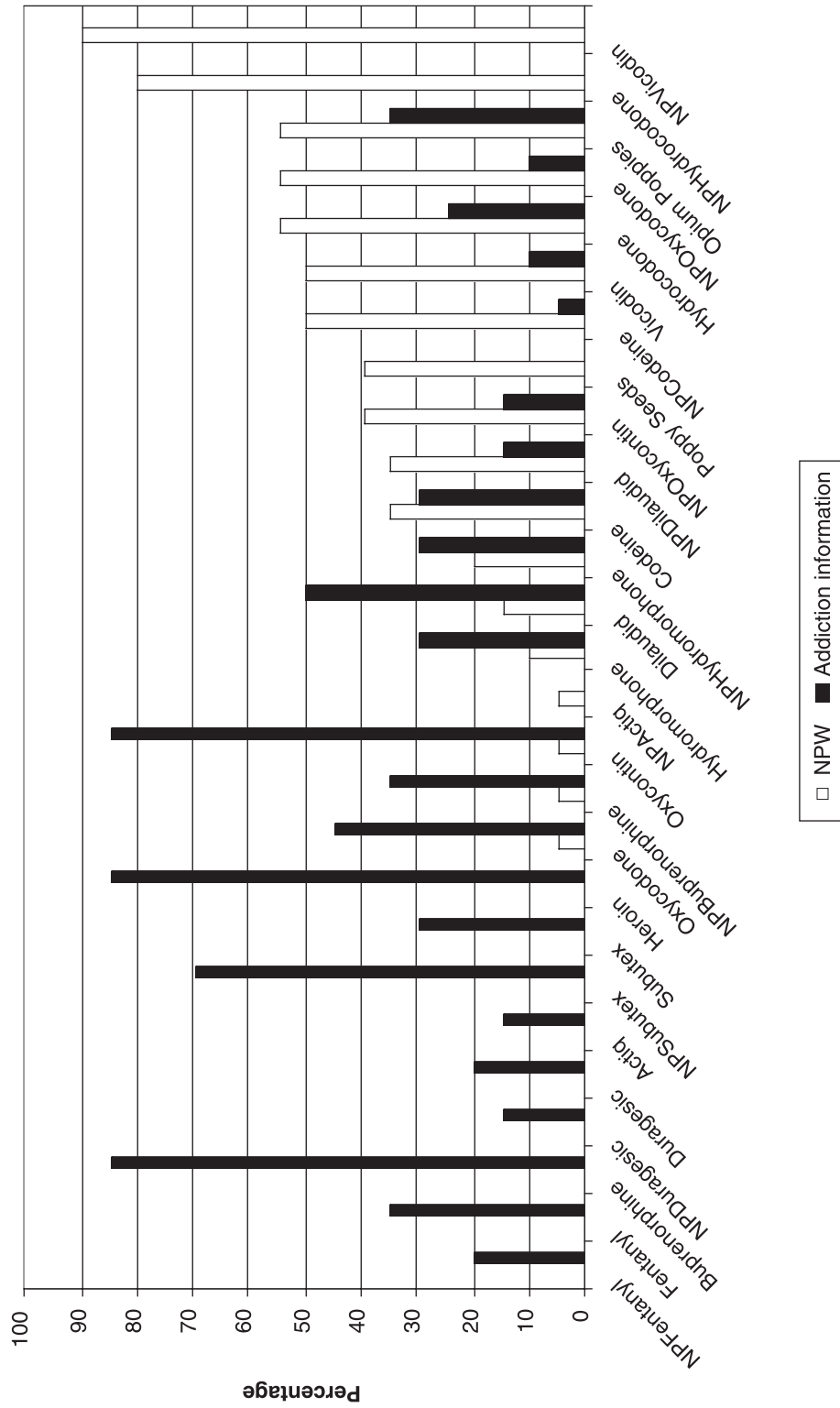
NPW Database

Since January 2003, all NPWs that offered to sell opioids were entered into a database maintained by the first author. As of August 12, 2005, the database included 426 NPWs, including 50 retail NPWs and 376 portal NPWs. Web sites included in this database were registered to 46 different countries, including the United States (60%). Almost all NPWs registered in the United States were portal NPWs, and the portals clearly dominated the search results when only the first 100 links were considered.

NPW Portals

As we noted previously, portal NPWs do not directly offer to sell opioid medications without a prescription but rather provide links to multiple NPWs. Because search engines preferentially rank Web sites that have “backlinks” (i.e.,

Figure 2. Relative Availability of NPWs Versus Addiction Health Information



Notes: NP = no prescription.

links coming into the Web site from other Web sites), portal NPWs tend to dominate search results (Forman et al. 2006). Because portals simply point to retail NPWs but do not directly sell opioid medications, they are not directly violating the Controlled Substances Act.

Purchases from NPWs

Because it is illegal to purchase prescription opioids and other controlled substances without prescription, there are limited data on the actual delivery rate of NPWs. However, the U.S. General Accounting Office (GAO) conducted an investigation in which it attempted to purchase prescription drugs without a prescription. In total, the GAO investigators placed 90 orders for prescription drugs without prescription; of these orders, 45 (50%) were filled. The GAO purchased a wide range of prescription medications, including 11 purchases of opioids. Of these 11 medications (including hydrocodone and oxycodone), 10 (94%) were delivered (GAO 2004).

In April 2005, the DEA, in conjunction with U.S. Customs and other national and international law enforcement agencies, completed its first investigation of international NPW operations. Operation “CyberChase” was concluded on April 20, 2005, with the arrest of 20 people in eight U.S. cities and four foreign countries (India, Costa Rica, Australia, and Canada). According to the DEA (2005a) report, since July 2003, the Bansal Organization distributed approximately 2.5 million dosage units of Schedule II–V pharmaceutical controlled substances per month, including Vicodin (hydrocodone), anabolic steroids, and amphetamines. The DEA report noted that the Bansal Organization operated more than 100 Web sites and maintained more than 40 bank accounts.

Three months later, the Miami DEA announced the conclusion of a nine-month investigation called “Operation Backroom,” which resulted in the arrest of eight people in Florida and one in Texas (DEA 2005b). According to this report, the operators of the Web sites, which were linked with 14 pharmacies based in Florida, filled more than 28,000 orders per week without a prescription, amounting to more than \$10 million in online orders for controlled substances, particularly hydrocodone, since 2003.

Awareness of NPWs

Beginning in the fall of 2003, the popular press began describing—and inadvertently publicizing—the availability of prescription opioids over the Internet without prescription. The earliest newspaper report on NPWs that we found was published on October 18, 2003, in *The New York Times* (Harris 2003) in an article that described a joint DEA/FDA task force targeting rogue online pharmacies that sold prescription drugs without a prescription. Two days later, *The Washington Post* released a five-part series that detailed the results of a one-year investigation into the availability of prescription drugs without a prescription (Gaul and Flaherty 2003a, c, d, f, e). A month after *The Washington Post* series, *USA Today* (Rubin 2003) reported on the “uncontrolled sale of controlled substances” over the Internet, and then in December 2003, news coverage about NPWs became widespread with the *Los Angeles Times* (Healy 2003), *Philadel-*

phia Daily News (DeWolf 2003), *Boston Herald* (Caywood 2003), *The Miami Herald* (Gaul 2003), *Denver Post* (Frates 2003), *San Jose Mercury News* (Anderson 2003), and the *Chicago Tribune* (Higgins 2003) publishing stories about the online availability of controlled substances without a prescription. In December 2003, Google also issued a press statement, announcing that it would no longer accept advertisements from unlicensed, rogue pharmacies though it would continue ranking and including NPWs in search results (Gaul and Flaherty 2003b).

The Use of NPWs by Addicted People

Gordon, Forman, and Siatkowski (2006) provide preliminary evidence of the awareness of NPWs among drug dependent people. In their study, which was conducted at a private residential addiction treatment program outside Philadelphia, 100 patients admitted for drug dependence were interviewed about how they had obtained the drugs they had used 30 days before entering treatment. In total, 9% reported that they purchased their drugs online, and an additional 2% stated that they had found their dealer online. In addition, 29% indicated that they knew they could purchase drugs over the Internet without a prescription. This sample did not include anyone less than 18 years of age; thus, it is unclear whether these findings would generalize to this younger, Internet-savvy demographic.

NPW Decoys

The DEA has launched an initiative to increase awareness of NPWs and to deter customer shopping from illicit Web sites by posting “decoy” NPWs. When a customer clicks on a decoy link obtained in a search, the Web page returned warns the customer that some Internet sites facilitate the illegal sale of prescription drugs and that they allow some consumers to purchase controlled substances illegally without realizing they are committing a crime. A clip-art image above this notice is that of a man in a prison cell, holding his head. Importantly, in the thousands of links by the first author and his staff, they have yet to encounter the DEA notice.

Identifying NPWs

Naive consumers may not be aware that they have ordered from an NPW, because most of these Web sites are attractive and professional in appearance (Gaul and Flaherty 2003c). As our content analysis reveals, NPWs often include medical images, pharmaceutical company logos, and other symbolism to establish their legitimacy. Neither the name of the Web site nor its URL provides clues as to their legal status, and many explicitly claim that they are legal. The single distinguishing criterion for NPWs is whether it requires a valid prescription before selling a DEA scheduled drug.

Some NPWs simply ignore the issue of prescription altogether; others ask the consumer to fill out an online questionnaire, which is purportedly evaluated by an affiliated physician for a fee; and some offer a telephone consultation, either free or for a fee, with a “health care professional” (GAO 2004). However neither telephone consultations nor

questionnaires can serve as a basis for a valid prescription, because a face-to-face examination by a licensed physician or other qualified health care professional is required (DEA 2001).

Distinguishing NPWs from legitimate online pharmacies can be difficult for consumers because NPWs convey legitimacy through placement of the kinds of visual and textual cues we described previously. Medical legitimacy may be conveyed through the use of pictures of people in white lab coats and the inclusion of health care images. Including third-party certification logos and customer testimonials implies the legitimacy of the retailer and the transaction itself. Another indicator of an illegal pharmacy is the placement of legal guidance on the Web site; some NPWs imply that they are complying with country-specific legal regulations, whereas others explicitly claim legal status. References to secure, discrete shipping methods are also prominent. Some NPWs suggest sending the drugs to a post office box, and others explicitly describe procedures for resending medications in the event the shipment is confiscated. The NPWs examined in our studies never mention participation in insurance or managed care plans.

Content Analysis of 50 Retail NPWs

Beyond qualitative examinations of typical NPWs, there has been no systematic study of the content of current retail NPWs. Understanding the content and prevalence of particular features of NPWs (e.g., shipping methods) may help guide policy for better monitoring and, ultimately, shutting down these illegal sites. Importantly, a systematic understanding of the content of NPWs can help in addiction treatment and guidance to patients who inadvertently encounter NPWs. Subsequently, we present the results of a content analysis of 50 current NPWs, after which we return to these policy and addiction treatment implications.

Procedure and Coding Scheme

We selected 50 NPWs included for content analysis by examining links within the top three portal NPWs identified during a search conducted in June 2005. During the coding process, we eliminated from consideration any Web site found to be a legitimate retailer that sold medication only to customers with a doctor's prescription and replaced it with the next linked Web site until we reached 50 NPWs.

We developed a coding sheet to classify NPW content relevant to policy and marketing. The categories are as follows: (1) attempts to imply legitimacy or credibility, (2) claims of medical consultation, (3) shipping information, (4) payment information, and (5) offers to sell other abusable medications (Forman et al. 2006). These five categories represent the characteristics that are most likely to influence customer purchase from an NPW. Table 1 provides a complete list of the categories with examples from NPWs that typify such content.

Implied legitimacy and credibility claims. We coded for 12 indicators of implied legitimacy or credibility. These included three subset categories of (1) medical legitimacy, (2) explicit or implied legality, and (3) retailer credibility. Medical legitimacy claims include visual cues, such as pic-

tures of lab coats or the presence of "Rx" and other health care symbols, and prescription indications and restrictions. We also documented cases of explicit legality, such as when the Web site claims to be legal, and implied legality, such as references to laws, age restrictions, or FDA approval. In addition, we identified cases in which the operator attempted to promote retailer credibility by including customer testimonials or any logo or other symbol of third-party certification.

Medical consultation claims. We coded for seven elements of medical consultation claims in the NPWs. These included classifications to determine who would provide the consultation (e.g., physician, health care professional) and whether the Web site required a medical consultation directly, over the telephone, or through an online questionnaire filled out during the ordering process.

Shipping claims. We coded for shipping information along six measures. These included whether the Web site ensured discrete or secure shipping, mentioned the risk of seizure by customs, or listed the name of a delivery company.

Payment claims. We coded for payment information by form of payment (e.g., check, cash on delivery, or credit card). We also distinguished between Web sites that took direct orders and those that required membership to order.

Offer to sell other abusable prescription medications. Finally, we documented whether the Web sites offered to sell customers other abusable prescription medications, such as sedatives, stimulants, or steroids. Because most NPWs sell a multitude of controlled medications, coders simply indicated the existence of an offer for any other medications (1 = offer made; 0 = no offer made).

Two assistants were instructed to independently code the Web sites for each variable on the coding form. The coders examined the Web sites within a few days of each other to minimize the risk of discrepancies due to changes on the Web sites and to ensure that the information on the Web site was the same for each coder's independent analysis. The 50 links were coded by both raters between July 8, 2005, and August 2, 2005.

The assistants analyzed the home page and immediate sublinks from the home page (e.g., "Frequently Asked Questions," "Shipping Policies," and "About Us" sections) to record the majority of the variables on the coding form. The coders then chose a prescription medication and pretended to order the product up until the point at which the Web site asked for a form of payment. This enabled them to collect information on variables that were not often included on the homepage or sublinks, such as whether the Web site had age restrictions on orders, required a membership, or included indications and contradictions.

Intercoder Reliability

Two coders received extensive training (through online conferencing) on the coding sheet and the definitions of the categories. Each assistant independently coded all 50 Web sites for the aforementioned 35 categories. The interrater

Table 1. Content Analysis Results and Coding Examples

Classification	Percentage of NPWs	Example 1	Example 2
Implied Legitimacy and Credibility Claims			
Medical Legitimacy	82		
Pictures of lab coats	44	Images of people in lab coats	Images of people in doctor's scrubs
Rx/health care symbol	16	Red Cross logo	Caduceus image
Pharmaceutical logos	44	Oxycodone logo	Vicodin pill image
Indications	66	Ultram is an analgesic most commonly used to treat or prevent moderate to severe pain.	This medicine is used for patients who need relief from mild to moderate pain.
Contraindications	60	Do not exceed the recommended dose or take this medicine for longer than prescribed.	Before taking this medication, tell your doctor if you have an allergy to aspirin or any other [nonsteroidal anti-inflammation drugs].
Legal Legitimacy	72		
Government logos	8	FDA logo	HIPAA (Health Insurance Portability and Accountability Act) logo
Explicit claim to be legal	30	Is this legal? Yes. We provide you with a paramedical exam completed by a licensed healthcare professional in your state on our behalf.	Order all the prescription drugs you need without a prescription ... legally!
Implied legality through reference to laws	30	We have developed comprehensive delivery systems that work very efficiently and fully comply with most countries' importation regulations.	Most countries allow three months' legal supply of prescription drugs, but we advise you to always check with your countries laws and regulations.
Age limit/restriction	24	You must be at least 21 years of age to use this service.	The minimum age of eligibility is 25 years of age.
FDA approval	30	Our company is your convenient, safe, and private source for FDA-approved prescription medications.	All made in the United States, and all are FDA approved.
Retailer Legitimacy	24		
Customer testimonials	16	Just wanted to say thanks again; you have made my life a lot more productive. Thanks for the great service.	I just wanted to thank you guys for your very, very fast service. I suffer from severe back pain, and the delivery of your product has been the best I have experienced.
Third-party certification	12	Verified by Visa logo	Master Card securicode logo
Claims of Medical Consultation			
Physician	56	You simply call the doctor at the time that suits you, and our friendly doctor will prescribe anything that he feels necessary and that is suitable for your condition.	The online medical consultation with a licensed U.S. doctor to get your prescription is free!
Health care professional	20	All consultations are with licensed, reputable health care professionals who will give you the best care and service possible.	Receive a phone call from a medical professional to discuss your medical condition.
Type of Consultation			
Free over telephone	8	No membership fee! No consultation fee!	U.S. doctors providing phone consultations. No consultation fees.
For fee by telephone	20	On a successful diagnosis by your physician, we will charge your credit card in the amount of \$110 for your physician consultation fee.	The cost of the phone consultation is US\$95.00.

Table 1. Continued

Classification	Percentage of NPWs	Example 1	Example 2
In person	2	We will schedule an exam for you at a cost of \$70.00 for the exam at your home or their local office.	—
Medical questionnaire “required”	52	You must answer an online medical questionnaire, similar to that which you would fill out in your doctor’s office.	You must complete the online medical questionnaire, which will ask you various questions related to previous treatment for your condition. This information will assist our physicians in managing your medical issues and treatment.
Health professional review required?	42	Find prescription drugs online with no prescription.	We guarantee no waiting rooms and no appointments.
Shipping Claims			
Offer secure shipping	52	All orders are sent by registered mail.	Must have an adult sign for the package.
Secretive shipping	70	Worldwide delivery in discrete packaging.	Your privacy is ensured!
Offer to reship if seized	2	If your package is refused, it will simply be returned and we will resend it or refund your money.	—
Risk of seizure by U.S. customs	6	If a package is turned away, it is typically due to a difficult customs officer instead of an official countrywide policy.	Before ordering, please check that there are no import Restrictions on this product in your country.
Free delivery	24	Free shipping worldwide.	Free worldwide shipping
Delivery company	52	FedEx	DHL
Payment Options			
Method			
Cash	12	We accept cash on delivery for established clients.	All orders are cash on delivery.
Payment <i>after</i> delivery	4	You send payment after you have received the sample and are happy with the product.	Send payment after you have received the shipment and are happy with the product.
Credit cards	88	Currently, we are unable to accept MasterCard. We can however accept Visa, Discover, and American Express.	Visa logo
Check	28	Pay by check.	Picture of a check
Money order	16	We accept only cashiers’ checks or money orders.	Picture of a money order
Western Union	6	E-mail for Western Union instructions.	Western Union logo
PayPal	6	Paypal verified Web site	Paypal logo
Other	10	Pay by cash wire.	Veripayment.com
Membership fee required	12	Join today. You’re just one click away from tremendous savings!	Choose your payment method below for instant access to our members section.
Sell Other Abusable Medications	98	Sedatives, stimulants, steroids	Sedatives, stimulants, steroids

reliability was high, with 98% overall agreement (thus, disagreement in only 29 of 1750 judgments). Total agreement (100%) was achieved through resolution with a final online conference call. For the 35 coded variables, all kappas (Kelly et al. 2000) were greater than the traditional .70 standard, and all but 4 were above .80.

Results

Claims of Legitimacy

Nearly all (92%) of the NPWs contained an implied legitimacy or credibility claim of some kind. In addition, 82% contained a medical legitimacy claim, 72% had an implied legality claim, and 30% made explicit claims of legality (e.g., “Is this legal? Yes”; see Table 1). Fewer NPWs displayed a retailer legitimacy claim (24%). A detailed breakdown of the percentage of NPWs containing each specific coded element is available in Table 1. For example, almost half (44%) of all NPWs displayed pictures of people in white lab coats, and an equal number (44%) displayed pharmaceutical logos or images.

Payment and Delivery Methods

Table 1 provides the results for all the coded variables. Note that 88% of NPWs accepted payment with one of the major credit cards, and more than half (52%) mentioned delivery through a reputable carrier, such as FedEx or DHL. This provides reassurance that working with credit card and shipping companies is a viable mechanism for identifying ownership of NPWs and potentially suspending their credit card contracts.

Medical Consultation

As Table 1 also indicates, approximately half (52%) of NPWs required some kind of online questionnaire to be filled out by the patient; a much smaller percentage offered a telephone consultation, either for free (8%) or for a fee (20%). Not surprisingly, but worthy of note, only 2% of NPWs made in-person medical consultations available; importantly, online pharmacies that required an in-person medical examination before issuance of a prescription were not coded as NPWs.

Innovative NPW Marketing Tactics

Although our content analysis summarizes the commonalities among NPWs, some of these sites are notable for their marketing savvy. Because all these Web sites were operational at the time of this writing, we do not provide their name or URL. However, interested readers can repeat our procedures and readily view these Web sites on their own. The following discussion provides examples of unique marketing tactics employed by specific NPWs that we identified in our monitoring studies.

Free Samples

A retail NPW offered free samples of opioid medications without prescription, stating that “[t]he company will send one free sample [of 3–5 codeine tablets] per new customer.”

If the customer is satisfied with the free samples, he or she is asked to send \$5 in cash to the company; the company will then advance the customer an additional 20 doses of codeine. If the customer pays cash for those 20 doses, the company will then ship 40 tablets.

Recreational Drug Use Advocate

A retail NPW explicitly stated that “if you are a recreational user, so be it; it is your personal right to do what you want in the privacy of your home.” This NPW required a monthly membership fee of \$25 but, in return, advertised morphine, opium, and OxyContin among its available medications.

Consumer Reviews

One portal NPW offered more than 200 links to retail NPWs, with consumer ratings of the online pharmacies and warnings if complaints had been registered against the site.

Confiscation Guarantee

A retail NPW provided a “confiscation guarantee” in the event that the shipment is interdicted by U.S. Customs. The Web site advised that the customer should provide the company with a copy of the confiscation and a “different name and mailing address.”

“Christian” NPWs

A Web site advertised itself as a “Christian Site for the Whole Family” with links to “Bible study groups,” “Christian News,” and “Christian magazines.” This site also had multiple links to NPWs offering to sell opioids and other controlled medications without prescription. A portal NPW announced an “Easter Drugs Sale: Buy Codeine Online Without Prescription.”

Policy Implications and Recommendations

The availability of NPWs is a challenge to international drug policy, regulation, and public health. Public health policy in most countries recognizes that addictive substances should be made available only under the guidance of qualified health care professionals, such as physicians and pharmacists. Adolescents, young adults, and the mentally and physically ill all incur increased rates of morbidity and mortality when restrictions on drug access are eased (Hawkins, Catalano, and Arthur 2003). Although the prescription drug reimportation debate centers largely on drug price and safety, the Controlled Substances Act is intended to protect the public from drugs that are of poor quality or over which people are at risk of losing self-control. Consequently, the purchase of opioid medications and other controlled substances is legal only when a valid prescription has been obtained subsequent to a face-to-face examination by an appropriately licensed health care professional.

Ongoing NPW-monitoring studies indicate their consistent high availability since January 2003, with the only important new trend being the emergence of the former Soviet block countries as NPW host countries. Just as “street-corner” drug dealers are readily replaced if they are

arrested, NPWs quickly appear and disappear. Given a potential market of more than one billion people, hundreds of millions in sales, low start-up and operating costs, loyal (addicted) customers, and enforcement complications, the Internet appears to be an enduring new route for drug trafficking.

The two successful enforcement operations we described previously in this article targeted major NPW organizations based in the United States. Such efforts may ultimately prove successful in shifting drug operations to foreign countries that do not restrict access to these medications or do so in a relaxed manner. With approximately 200 potential host countries and the ability to create and dismantle sites within hours, NPWs present a unique challenge not just to U.S. drug enforcement but also to similar agencies worldwide.

There are four potential “choke points” for enforcement efforts. These are (1) search engines that list NPWs when searches are conducted, (2) credit card companies with which NPWs and their customers have accounts, (3) package delivery companies, and (4) Internet service providers (ISP) with which NPWs files are hosted (Zittrain, in press).

Search Engines

The major search engines employ sophisticated proprietary algorithms to determine which Web sites will be returned when an individual conducts a search. Currently, searches using terms such as “no prescription codeine” reliably yield a high proportion of links that lead to Web sites that offer to sell this medication without prescription. In principle, the leading search engines could voluntarily elect to exclude from their search results Web sites that have been determined to be NPWs. However, this enforcement activity is one that search engines may be reluctant to assume. Some considerations that might make blocking NPWs acceptable include, but probably are not limited to, the following: (1) if all major search engines agreed to employ an identical blocking scheme and criteria and (2) if a governmental agency, with appropriate checks and balances, took responsibility and liability for determining whether a Web site was an NPW. The precedent for cooperating in this manner has already been set with the implementation of a SquareTrade policy for all advertisements accepted on Google and Yahoo (see our subsequent discussion of SquareTrade in the “Voluntary Efforts” subsection).

Credit Cards

As our content analysis revealed, 88% of NPWs accepted payment by credit cards. Consequently, a voluntary decision on the part of the major credit card companies not to do business with NPWs is another disrupting strategy that might be pursued. As with search engines, it is likely that credit card companies will be reluctant to implement such a plan unless it is universal for all major cards and a governmental agency takes responsibility and liability for the identification of illicit Web sites.

Delivery Company

About half of all the NPWs in our content analysis identified the specific delivery service employed, including several

well-known international companies. Moreover, regardless of whether an NPW identifies which delivery company it uses, ultimately, packages must be delivered in some way. Consequently, the same list of NPWs that is prepared for the credit card and search engine companies could be presented to the leading national delivery companies as well.

ISPs

Finally, every Web site must be hosted on an ISP. Therefore, a final choke point could be squeezed by encouraging all ISPs with business in the United States to cooperate by not doing business with NPWs.

If these four categories of firms cooperate in a voluntary effort to eliminate the availability of NPWs, the illicit sale of controlled substances over the Internet would be severely disrupted, at least temporarily. However, it is reasonable to assume that NPWs may not simply retire as a result of these efforts.

Cat and Mouse

Several federal agencies must cooperate in their efforts to investigate NPWs, including U.S. Customs, the DEA, the U.S. Postal Inspectors Office, and the FDA. Through a coordinated, multiagency effort, credit card purchases can be made from an NPW, thus creating an electronic trail that includes the NPW registration, its bank, its ISP, and its delivery company. All these links in the NPW operation can be notified that they are parties to illegal drug sales. With such notification, these commercial interests would be obligated to evaluate their participation and possibly cease involvement in a known criminal enterprise. Failure to do so may provide grounds for subsequent legal action and prosecution if the parties continue to work with an NPW, despite having received notice. If consistently applied, this simple enforcement effort could substantially disrupt NPWs.

The majority of NPWs included in our content analysis used major credit card and delivery companies, adding both credibility and ease to the transactions. Credit card and delivery companies are not investigative or enforcement agencies, however, and may be reluctant to voluntarily assume that role without a clear mandate. Although following the credit card e-trail offers promise for disrupting current NPW operations, ultimately it might drive NPWs to adopt alternative financial strategies rather than cease operations altogether. Just as street-corner dealers and their suppliers prefer cash, it may ultimately become the required practice for NPWs. Our content analysis revealed that 12% of NPWs (6 of the 50 NPWs) accepted cash on delivery only, and another 4% extended credit in advance to their customer to pay after delivery, thus taking all the financial risk in the transaction. Similarly, 28% of the NPWs accepted checks.

In addition to switching from credit cards to cash, NPWs may also increase their use of the privacy made possible by the Internet. Web sites have been identified that offer to sell marijuana only to people who are using anonymizing e-mail services, such as www.hushmail.com (Forman et al. 2006). E-mail encryption services further complicate the task for law enforcement by placing yet another level of privacy between the buyer and the seller. As law enforcement efforts

proceed, it is likely that NPWs will offer seamless integration of encryption services.

Voluntary Efforts

Search engines have voluntarily limited sponsored advertisements from online pharmacies that have been approved by SquareTrade (www.squaretrade.com), a company that verifies that the online pharmacy is hosted in either the United States or Canada and that the online pharmacy is “trustworthy” (Gaul and Flaherty 2003b). Importantly, this voluntary restriction does not apply to Google’s listing of Web sites in its searches, just the sponsored links. However, when the term “no prescription Vicodin” was used on both Yahoo and Google (on September 9, 2005), our examination of the sponsored links revealed several advertisements from NPWs. In other words, despite the claims by search engines that they do not accept advertisements from NPWs, both the page ranking and the advertisements make NPWs readily available in these search engines.

The problem faced by the search engines is similar to that faced by the three other potential choke points in the NPW distribution chain. These commercial enterprises are not enforcement agencies and are reluctant to take up that role without a clear mandate to do so. Given the foregoing discussion, it is likely that the availability of opioid medications and other controlled substances over the Internet without prescription will continue for some time. For this reason, a public health response is also required.

Public Health Response

Unsolicited e-mail offers from NPWs can be particularly destructive for people who are addicted to prescription opioids and to people who are in recovery from drug addiction. Such e-mails offer variety, convenience, and relative anonymity, lowering the barrier to potentially addictive drugs while creating an aura of legitimacy. Health care providers who work with addicted people need to develop assessment and treatment approaches that effectively address the needs of patients who buy their drugs online, without unintentionally disseminating information about NPWs. People in early recovery may be particularly vulnerable to relapse when confronted with an e-mail drug offer; consequently, patients should be advised to change their e-mail address, employ filtering software programs, or restrict their use of e-mail and the Internet, particularly during early stages of recovery when chances for relapse are the highest.

Although increased prescription opioid use by young people coincides with the emergence of NPWs, currently there is no evidence that NPWs cause this increased use. Nonetheless, given young people’s proclivities to “experiment” with drugs and the easy availability of addictive substances over the Internet, prevention efforts should begin to consider how to address the growth of NPWs. Because the Internet is a significant resource that students use for health information and because search engines are the primary portal through which searches for health information occur (Lenhart, Madden, and Hitlin 2005; Pew Internet & American Life Project 2005), the role of the Internet in promoting drug abuse among young people warrants further study (Boyer, Shannon, and Hibberd 2001). For example, teachers

who assign research reports on prescription opioids will unintentionally expose students to Web sites that promote and sell these medications without prescription.

Exposure to the problem of NPWs either through classroom assignments or through news stories and publicity can help deter NPW operations through education. Moreover, increased awareness about these phenomena may increase public pressure on private companies (e.g., Google, Yahoo) and the federal government to address the problem. Without sufficient public concern, it may be difficult for the federal agencies to devote sufficient resources to attacking this problem. However, there is still a significant portion of people who are largely ignorant of NPWs for whom inadvertent exposure may serve to facilitate the growing NPW market.

There is also a role for a more formal education process. As our content analysis shows, more than 80% of NPWs contain implied claims of medical legitimacy, with nearly half of them displaying “doctors” in lab coats and pharmaceutical logos. Likewise, more than 70% imply legal legitimacy in some form, with an astounding 30% of NPWs displaying explicit claims of legality. Although there is no realistic way to remove this “cloak of legitimacy” or to deter NPWs from fostering these deceptive inferences, venues of health information (e.g., physicians, clinics, medical Web sites) can be used to educate consumers. For naive consumers who unwittingly use NPWs, such educational efforts might prove fruitful. Similarly, NPWs have not yet appropriated the VIPPS logo, and thus it remains a viable means of distinguishing legitimate online pharmacies from NPWs.

There are many consumers who use NPWs purposefully to subvert U.S. regulations for delivery and sale of a controlled substance. As our content analysis shows, they have ready access to NPWs that offer free/fee telephone consultations (28%) or online questionnaires (52%). Note that only 2% of the NPWs included in our analysis offered in-person medical exams. Perhaps a public health response could include an “out-of-the-box” reevaluation of drug strategies to compete with the use of the Internet for these purposes. Specifically, Web sites offering free, confidential referrals to physicians and clinics that provide treatment for opioid dependence could post advertisements in search engines tied to search terms such as “no prescription Vicodin.” In this manner, offers of professional treatment will compete with offers of illicit drug use.

In little more than a year, the music industry was radically transformed by the appearance of music file-swapping Web sites such as Napster. Young people who wanted the latest music free of charge enthusiastically embraced these Web sites, whereas music industry executives, Internet libertarians, and intellectual property regulators wrestled over how to best address online file swapping. However, when a music industry outsider, Apple Computer, launched its enormously popular and now widely imitated iPod and iTunes, the debate quietly receded into the background. Apple had an opportunity to compete effectively with the illegal file-swapping Web sites by offering customers an attractive medium for buying songs.

By analogy, the emergence of NPWs may force a reevaluation of current drug control strategies. Along with the emergence of NPWs and increased opioid medication

abuse, recent advances in medication development and regulation have produced new medications for the treatment of opioid dependence, such as buprenorphine. Buprenorphine acts on the same brain systems as the commonly used opioid medications but with a greatly reduced potential for abuse and overdose. By increasing the availability of this and similar medications, the public health system has added an option to methadone maintenance. Similarly, other novel addiction medications are being developed for the treatment of stimulant dependence. Although addiction treatments have been available for more than 100 years, medications such as buprenorphine represent a significant advancement in that they may be more successful in competing with illicit opioids, not just neurochemically but also in the public mind. Because methadone maintenance and other traditional addiction treatments can be provided only by specially licensed addiction treatment programs, people who sought care from traditional providers needed to overcome the unfortunate stigma that has been associated with these programs. Conversely, buprenorphine may be prescribed by any physician who completes eight hours of training and provides counseling on-site or by referral. These new options could make treatment easier to access for addicted people and may be able to compete successfully with the Internet for those who need opioid maintenance.

Studies of NPW monitoring have established the ongoing and stable availability of Web sites that offer to sell opioid medications without prescription. Despite existing laws and law enforcement efforts at both the state and the federal level, NPWs continue to market opioids and other controlled medications openly without prescription. The virtuality and global nature of the Internet make it an appealing medium for both buyers and sellers of controlled substances. It is unknown whether the current availability of NPWs is a permanent feature of the illicit drug landscape or a temporary anomaly that will eventually be brought under control. Ongoing research should continue to monitor the availability of NPWs, assess their impact on public health, and develop strategies to reduce their adverse effects on vulnerable populations.

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