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Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales

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ABSTRACT

Online sales of pharmaceuticals are a rapidly growing phenomenon. Yet despite the dangers of purchasing drugs over the Internet, sales continue to escalate. These dangers include patient harm from fake or tainted drugs, lack of clinical oversight, and financial loss. Patients, and in particular vulnerable groups such as seniors and minorities, purchase drugs online either naïvely or because they lack the ability to access medications from other sources due to price considerations. Unfortunately, high risk online drug sources dominate the Internet, and virtually no accountability exists to ensure safety of purchased products. Importantly, search engines such as Google, Yahoo, and MSN, although purportedly requiring "verification" of Internet drug sellers using PharmacyChecker.com requirements, actually allow and profit from illicit drug sales from unverified websites. These search engines are not held accountable for facilitating clearly illegal activities. Both website drug seller anonymity and unethical physicians approving or writing prescriptions without seeing the patient contribute to rampant illegal online drug sales. Efforts in this country and around the world to stem the tide of

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these sales have had extremely limited effectiveness. Unfortunately, current congressional proposals are fractionated and do not address the key issues of demand by vulnerable patient populations, search engine accountability, and the ease with which financial transactions can be consummated to promote illegal online sales. To deal with the social scourge of illicit online drug sales, this article proposes a comprehensive statutory solution that creates a no-cost/low-cost national Drug Access Program to break the chain of demand from vulnerable patient populations and illicit online sellers, makes all Internet drug sales illegal unless the Internet pharmacy is licensed through a national Internet pharmacy licensing program, prohibits financial transactions for illegal online drug sales, and establishes criminal penalties for all parties—including websites, search engines, and health care providers—who engage in and facilitate this harmful activity.

I. INTRODUCTION

The Internet is perhaps the most widely utilized technological innovation in the past twenty years. U.S. Census Bureau data from 2006 shows that over 200 million adults access the Internet.[1]

Tremendous benefits have resulted from the explosion of business and trade that has accompanied the Internet. By greasing the wheels of commerce, the Internet has provided significant reductions in cost and greater access to more products for more people around the world. Indeed, globalization of commerce is part and parcel of Internet transactions.

However, with such an increase in online sellers and willing buyers, the darker side of Internet sales has emerged. One area is particularly worrisome: the sale of medications over the Internet. Unscrupulous and nefarious individuals have entered this market, eager to sell tainted, fake, and poor quality drugs to anyone with a credit card and the willingness to pay. These sales are often not only an illicit means of profit but are also a foundation for additional criminal activity.[2] Physician oversight of care is left behind, and those who purchase these drugs take the risk that they will not get anything that they purchase, or worse, that they will get tainted medicines that do not effectively treat their disease(s) or may even harm or kill them.[3]

With unfettered Internet drug sales threatening public health, policymakers must be informed about this issue so that they can take the necessary steps to address the problem and allow the benefits of Internet purchasing to inure to patients.[4]

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[1] *See* U.S. Census Bureau, Statistical Abstract of the United States: 2008 718 (2008), *available at* http://www.census.gov/prod/2007pubs/08abstract/infocomm.pdf.

[2] Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 Am. J. L. & Med. 279, 285-287 (2006).

[3] Bryan A. Liang, *A Dose of Reality: Promoting Access to Pharmaceuticals*, 8 Wake Forest Intell. Prop. L.J. 301 (2008).

[4] If done correctly, there are also some legitimate potential benefits that Internet pharmacies offer as a delivery model over traditional "brick and mortar" pharmacies that consumers have cited as reasons for purchasing online. These include 24/7 access, convenience of delivery to one's home, and more efficient centralized order-processing systems to reduce overall cost passed on to the consumer. *See* Constance. H. Fung et al., *Controversies and Legal Issues of Prescribing and Dispensing Medications Using the Internet*, 79(2) Mayo Clin. Proc. 188, 189 (2004).

In Part II, we review the problem of online drug sales. The scope of Internet drug sales is burgeoning, and the dangers from these purchases are numerous, particularly for vulnerable patient populations. Despite warnings from government, law enforcement, and public health organizations, patients continue to purchase from suspect online sellers either because of lack of education or because in-person access to drugs presents challenges. Unfortunately, the Internet drug sales world is populated by unethical sellers and questionable providers that allow virtually any drug to be purchased with impunity.

In Part III, we discuss the lack of accountability and oversight of Internet search engines. Profits from advertisements incentivize search engines to maximize their numbers of online advertisers. Although Internet search engines purportedly "verify" the legitimacy of Internet drug sellers through PharmacyChecker.com, in fact, little verification of the potential advertisers actually takes place. "Verified" pharmacies sell fake drugs and do not fulfill the supposed verification "requirements." Both the pharmacy and the Internet search engine profit from the advertisements of non-verified pharmacies.

Part IV documents U.S. and worldwide attempts to limit the illicit use of the Internet for illegal drug sales and the ineffectiveness of these efforts. Regulatory efforts by organizations including the World Health Organization ("WHO"), domestic oversight agencies, and law enforcement have been hampered by a lack of regulatory infrastructure and enforcement power.

In Part V, we outline congressional proposals to address the problem of illicit online drug sales. Unfortunately, these proposals are fractionated and none comprehensively address the problem or the issue of search engine accountability.

In Part VI, we propose a federal bill that would address the key issues of illicit demand by vulnerable patient populations by creating a national no-cost/low-cost Drug Access Program to provide these groups with access to drugs without the need to use questionable online sources. In addition, the bill would create search engine accountability for facilitating illegal online sales by prohibiting any receipt of financial transaction proceeds for unlawful Internet pharmacy drug requests. The bill would establish a national licensing system that only allows legitimate Internet pharmacies to sell drugs online. Finally, and perhaps most importantly, the bill would create criminal offenses and strong penalties for all parties who participate in facilitating and engaging in the dangerous activity of illegally selling drugs online, including websites, search engines, and health care providers.

Part VII of the paper offers some concluding remarks. We call for a much more aggressive focus on Internet online drug sales, and for policymakers to ensure that systems be created to ensure no person need ever bet their lives or their families' lives on the safety of an online drug.

II. ONLINE DRUG SALES

A. Scope of Online Drug Sales

The business of selling prescription pharmaceuticals over the Internet has fueled an industry that analysts estimate generated from $15-20 billion in sales in 2004.[5] Yet the illicit nature of online drug sales is apparent. For example, a detailed study of online drug sellers indicated that fully eighty five percent of websites offering drugs for sale required no prescription from a patient's physician.[6] To make matters worse, of the fifteen percent of sites offering drugs online that "require" a prescription, only half ask that the prescription be faxed, introducing tremendous opportunities for fraud and circumvention of legitimate and important physician oversight.[7]

The exact number of Internet drug sale sites[8] on the web is difficult to determine accurately due to the fact that illegitimate or "rogue" Internet drug sellers, which open and close with high frequency, often have several URLs for one company, and may only be transiently listed on select search engines.[9] As a reflection of this reality, a simple Google search at any given time using "Internet pharmacy" as the search term will reveal millions of results.[10] As might be expected, government officials trying to regulate these online sellers have had little success due to the sheer volume of sellers.[11]

These Internet drug sellers are of great concern with respect to consumer safety. Many are of international origin, advertise purchasing drugs without a

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[5] *See* Stephanie Y. Crawford, *Internet Pharmacy: Issues of Access, Quality, Cost, and Regulation*, 27(1) J. Med. Syst. 57, 58 (2003) ($20 billion estimate); Amy J. Oliver, *Internet Pharmacies: Regulation of a Growing Industry*, 28(1) J.L. Med. & Ethics 98, 98 (2000) ($15 billion estimate).

[6] *See* National Center on Addiction and Substance Abuse at Columbia University, "You've Got Drugs!" V: Prescription Drug Pushers on the Internet 1 (2008), http://www.casacolumbia.org/articlefiles/531-2008%20You%27ve%20Got%20Drugs%20V.pdf.

[7] *See id.* at 2. Indeed, in a 2007 hearing before the Senate Judiciary Committee, it was reported that Internet dealers of controlled substances increased by over 70% in the last year. *See Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking: Hearing Before the S. Judiciary Comm.*, 109th Cong. (2007) (statement of Joseph Califano, Jr., Chairman and President, National Center on Addiction and Substance Abuse at Columbia University), *available at* http://judiciary.senate.gov/hearings/testimony.cfm?id=2755&wit_id=6464. However, details regarding online sales of these controlled substances indicates escalating dangers. The Drug Enforcement Administration ("DEA") in its investigations found that in 2006, fully 95% of all Internet prescription sales involved controlled substances, compared with a *maximum* of 11% of those types of prescription drugs filled in traditional, regulated pharmacies. *See* National Center on Addiction and Substance Abuse at Columbia University, *supra* note 6, at 4. DEA concluded that on the basis of these figures, unregulated online sales are primarily drug purchases for abuse. *See id.*

[8] We avoid the use of "Internet pharmacies" in this paper because the websites of interest that are selling drugs are not true pharmacies, but instead are illicit operations.

[9] *See* National Center on Addiction and Substance Abuse at Columbia University, *supra* note 6, at 5-6 (describing portal, anchor, and Internet drug seller pyramid); National Association of Board of Pharmacies – Frequently Asked Questions, http://www.nabp.net (last visited Feb. 1, 2009).

[10] Internet search of the words "internet" & "pharmacy," Google.com, May 9, 2008.

[11] *See* Erick Eckholm, *Most Drug Web Sites Breaking Federal Law*, SFGate.com, July 9, 2008, *available at* http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2008/07/08/MNJ711M1KB.DTL.

prescription, and purport to have been approved by U.S. federal agencies such as the Food and Drug Administration ("FDA").[12] These Internet drug sellers represent the highest risk category for consumers given the inability of U.S. regulators to ensure quality and safety.[13] As noted by Joseph Califano, Jr., director of the National Center on Addiction and Substance Abuse, "anyone of any age can obtain dangerous and addictive prescription drugs with the click of a mouse."[14]

B. Dangers of Online Drug Sales

The dangers these websites pose are numerous and rather self-evident. All implicate consumer safety as well as financial security.[15] These dangers include: the delivery of drugs or active pharmaceutical ingredients without a valid prescription; lack of professional oversight; the risk of questionable quality, counterfeit or substandard product; poor or lack of medication instructions; failure to provide adequate independent information to patients on possible adverse reaction and drug interactions; fraud; inability for consumers to be reimbursed by health insurance programs; and lack of confidentiality of personal medical data.[16]

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[12] *Id.*; *see also* National Center on Addiction and Substance Abuse at Columbia University *supra* note 6, at 10 (using logos such as the Food and Drug Administration and the "American Drug Administration" as well as other logos to promote the image of legitimacy).

[13] *See* Frank B. Palumbo et al., *Policy Implications of Drug Importation*, 29 Clinical Therapeutics 2758 (2007) (noting increased risks of counterfeits and tainted medications through consumer drug importation using the Internet); National Association of Board of Pharmacies – Buying Medicine Online, http://www.nabp.net (last visited Feb. 1, 2009).

[14] *See* Eckholm, *supra* note 11.

[15] *See, e.g.*, Peter Gernburd & Alejandro R. Jadad, *Will Spam Overwhelm Our Defenses? Evaluating Offerings for Drugs and Natural Health Products*, 4 PLoS Med., Sept. 18, 2007, *available at* http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0040274&ct=1 (discussing study that found easily accessed online purchasing without a prescription from spam e-mail and reporting 2/3 orders resulted in no products); Patrick White, *No Prescription, No Problem*, globeandmail.com, Sept. 18, 2007, http://www.theglobeandmail.com/servlet/story/RTGAM.20070918.wldrugs18/BNStory/PersonalTech (reporting on the PLoS study).

[16] *See* Oliver, *supra* note 5, at 98; World Health Organization, Medical Products and the Internet: A Guide to Finding Reliable Information (1999), http://www.who.int/medicinedocs/index.fcgi?a=d&d=Js2277e.6&l=fr#Js2277e.6 (last visited Feb. 1, 2009); *see also* Jonathan Ma, *Lowering Prescription Drug Prices in the United States: Are Reimportation and Internet Pharmacies the Answer?*, 15 S. Cal. Interdisc. L.J. 345, 362-363, 370 (2006). Ma notes that:

> It is also not always an easy task to distinguish between a legitimate Internet pharmacy website and one that seeks to deceive consumers by selling adulterated or inappropriately prescribed drugs . . . . With current technology, it can also be quite easy for a company to shirk responsibility and avoid risk exposure for operating an Internet pharmacy simply by covering up the source of supplied medication and the responsible party . . . . Since an Internet pharmacy prescription is arranged without personal interaction, there is no practical way for a patient to verify a prescribing doctor's credentials or training or even the appropriateness of medical attention provided . . . . There is no way for a patient to ensure that a prescribing physician actually is who he claims to be and that the physician is practicing lawfully . . . . Other dangers posed to consumers using Internet pharmacies involve fraudulent or questionable business practices and consumer access to unapproved or counterfeit drugs . . . . [W]hen weighed

Importantly, the uninsured and underinsured populations represent a significant at-risk group purchasing from these sites. These patients do not have access to or often cannot afford to see a physician and may instead elect to purchase drugs and seek treatment online.[17]

Also, spam e-mail and other electronic solicitations are something every e-mail user is familiar with and have the potential to entice individuals who may not have had the original intention of purchasing online.[18] Large scale criminal operations may be behind spam e-mails that promote the illegal sales of counterfeit and poor quality drugs as well as those that infect purchaser computers with viruses.[19] These dangers, together with a number of well-documented patient tragedies[20] where patients have died because of drugs

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> against the serious health and safety risks associated with Internet pharmacies, the limited and uncertain potential cost savings do not make Internet pharmacies a viable solution to the problem of high prescription drug prices.

Id. (citations omitted).

[17] *See infra* notes 21-28 and accompanying text (discussing why consumers purchase online); *see also* Thomas Ginsberg, *Online Drug Bust is Casting a Wide Net: Some Customers with Valid Medical Needs Were Using the Internet Pharmacy. Experts Say Battling Sites Will Be Hard*, PHILA. INQUIRER, Apr. 22, 2005, at B1 (describing the case of patient Nina, who used an illegal online drug seller to obtain life-saving drugs after losing health insurance). It is interesting to note that at least some of the price differential driving high risk pharmaceutical purchasing may come from the legal system itself, or a "tort tax". *See, e.g.*, Brian Crowley, *Americans Pay Big Tort Tax on Drugs*, PROVIDENCE J., Jan. 6, 2009, *available at* http://www.projo.com/opinion/contributors/content/CT_crowley6_01-06-09_HVCQDKJ_v13.3e33db5.html (summarizing studies showing tort tax effect on pharmaceutical pricing that drives U.S. prices higher than Canada).

[18] *See Buyer Beware: The Danger of Purchasing Pharmaceuticals on the Internet: Hearing Before the Subcomm. on Investigations Comm. on Governmental Affairs*, 108th Cong. (2004) (statement of Karen Tandy, Administrator, Drug Enforcement Administration), *available at* http://www.usdoj.gov/dea/pubs/cngrtest/ct072204.html.

[19] *See, e.g.*, Joseph Menn, *Spammers Are Making Real Money on Fake Drugs*, L.A. TIMES, June 11, 2008, *available at* 2008 WLNR 10976454 (describing how major spammers created the virus Storm to infect millions of computers and has coordinated with Russian drug counterfeiter for large profits).

[20] *See, e.g.*, Joe Cantlupe, *Victim's Mother Pleads for Online-Drug Clampdown*, SIGNONSANDIEGO.COM, June 18, 2004, http://www.signonsandiego.com/uniontrib/20040618/news_1n18drugs.html (reporting on Ryan Haight, a 17 year old honors student who died because of prescription drugs obtained over the Internet). The Ryan Haight case illustrates the need for strictly regulated online drug sales to place a barrier between illicit sellers and vulnerable buyers. *See* Jarrod Booker, *Action Urged on Internet Drugs*, NEW ZEALAND HERALD, Sept. 30, 2008, *available at* http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10534908 (describing the case of mental health patient Graham David Goodwin who died after taking drugs ordered from an Indian mail order drug seller through the Internet); Drew Griffin & David Fitzpatrick, *Widow: My Husband Died from Online Drugs*, CNNHEALTH.COM, May 22, 2008, http://www.cnn.com/2008/HEALTH/05/21/online.drugs/index.html (describing case of patient who bought muscle relaxant prescription drugs online, became addicted, and overdosed); Sam Solomon, *BC Woman Killed by Fake Drugs Bought Online*, 4 NAT'L REV. MED. (2007), *available at* http://www.nationalreviewofmedicine.com/issue/2007/07_30/4_policy_politics_13.html (describing the case of Marcia Bergeron, a fifty-seven year old women who was killed by counterfeit drugs purchased online); Mallika Marshall, *Online Pharmacies: Dangerous Prescription?*, CBS NEWS, May 31, 2008, http://www.cbsnews.com/stories/2008/05/31/earlyshow/health/main4142407.shtml. Marshall notes that:

> One man who was suffering from severe back pain received an e-mail offering Xanax and Ultam, two pain-killers. He took one of each tablet, suffered a heart

purchased online, indicate the absolute need to address this growing phenomenon.

C. Why Consumers Purchase Drugs Online

Beyond perceptions of lower price,[21] why do consumers continue to purchase pharmaceuticals online given all the potential dangers and negative outcomes? The simple answer is that for some consumers, the benefits outweigh the potential dangers and/or consumers are not adequately informed or educated.

Often, buyers who enter the nontraditional market for drugs and risk receiving counterfeit and low quality materials have little knowledge of the scope or presence of that risk. Despite at least some information on the dangers of online purchasing,[22] online drug consumers have either not received the message or simply ignored it.[23] Indeed, a recent survey found fifteen percent of U.S. respondents had purchased drugs online.[24] Yet an incredible ninety-three percent of the respondents who had purchased pharmaceuticals via the Internet never considered that the products might be tainted or fake.[25]

Indeed, on deeper analysis, this lack of concern is even more worrisome. Despite the fact that more than half (fifty-three percent) of these online drug purchasers expressly noted that there is no way to tell if a drug is real or counterfeit, they still purchased the drug over the Internet.[26] Further, highlighting the naïveté or lack of education of these purchasers, more than a quarter of them (twenty-seven percent) said an online seller's guarantee that the medication was genuine was good enough for them.[27] Importantly, some of the most physically and financially vulnerable patient populations are

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> attack and went into a coma. The tablets contained four times the usual starting dosage. A woman who decided she suffered from chronic fatigue syndrome bought steroids online, and ended up with severe cataracts, so severe they couldn't be removed . . . . In some cases, the problem is the pills are either placebos, made of sugar with only a minimal amount of the drug in them. But some have been found to contain other substances that are dangerous, even potentially deadly. One offshore drugmaker was manufacturing Viagra tablets that were 85-percent cement. There are reports of Viagra that is actually made of vodka. Allergy medications were found to contain steroids, to suppress the symptoms. You just don't know what these counterfeit pills may be made of.

Id. *See infra* notes 143-52 and accompanying text (describing the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, a federal effort to respond to the dangers of Internet drug sellers).

[21] *See supra* note 17 and accompanying text. Note that unfortunately, many of the drugs ordered online by patients are not cheaper at the online site. *See, e.g.*, Press Release, U.S. Food and Drug Administration, FDA Finds Consumers Continue to Buy Potentially Risky Drugs Over the Internet: Practice Puts Consumers at Risk and May Be More Expensive than Domestic Purchasing (July 2, 2007) *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01663.html (noting large fraction of drugs purchased over the Internet available more cheaply in the United States).

[22] *See infra* Section IV.

[23] *See* sources cited *supra* note 20; *see also* National Consumers League, Counterfeit Drug Survey (2004), http://www.nclnet.org/pressroom/fakedrugsreport.htm.

[24] *See* National Consumers League, *supra* note 23.

[25] *See id.*

[26] *See id.*

[27] *See id.*

engaged in this high-risk activity. Seniors were found to be the largest age group to purchase from online drug sellers.[28]

D. Variation Among Online Drug Sellers

There is a high degree of variability in quality and safety among Internet drug sellers. Four major types of online drug sellers exist: (1) traditional, established chain pharmacies with a web presence; (2) independent community pharmacies with a web presence; (3) stand-alone, exclusively online pharmacy sites; and (4) rogue or illegal sites.[29] Internet sellers which are in the latter two groups, and which are by far the most numerous,[30] pose the highest risk to consumers.[31]

The risk of ordering through Internet drug sellers is often directly related to the manner of order, delivery, and the type of pharmacy the patient does business with. The spectrum of ordering methods demonstrates an increasing distance from legitimacy and oversight that increases risks associated with the purchase, sale, and use of the product. Ordering methods include consumers: (a) mailing in a legitimate prescription; (b) having their physicians submit prescriptions by phone, fax or mail to an online distributor; and (c) obtaining a prescription from the website itself through an online "survey."[32]

The latter ordering method is of particular concern. The use of "cyber doctors" through which consumers may fill a prescription simply by responding to a scripted online questionnaire eliminates physician oversight of potential adverse reactions, allows purchasers to provide inaccurate and/or false information, and results in situations where patients forego needed treatment.[33] Physicians who participate in such a scheme are contravening standards of the Federation of State Medical Boards, the American Medical

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[28] *See id.* Even in parts of the world where counterfeits are relatively well known, such as the EU, there is very limited knowledge as to the risks of counterfeits. *See, e.g.*, Katrina Megget, *Survey Asks: What to Do about Counterfeit Drugs?*, In-Pharma Technologist, Oct. 30, 2007, http://www.in-pharmatechnologist.com/news/ng.asp?n=80987-together-health-who-counterfeit-drugs-legal-intervention-impact (reporting on an EU study that found only 18% of patients were concerned about counterfeit drugs, reflecting "a worrying lack of knowledge among patients and patient organizations into the scale of the counterfeit medicines problems across Europe").

[29] *See* Stephanie Y. Crawford, *supra* note 5, at 57-58.

[30] *See Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking: Hearing Before the S. Judiciary Comm.*, 109th Cong. (2007) (testimony of Thomas McLellan, Chief Executive Officer, Treatment Research Institute), *available at* http://judiciary.senate.gov/hearings/hearing.cfm?id=2755 (describing study by which TRI estimated that close to 80% of online pharmaceutical sites originate from outside the United States and import drugs illegally).

[31] *See* Marshall, *supra* note 20.

[32] *See* Oliver, *supra* note 5, at 98-99. Other methods include transferring existing prescriptions to Internet pharmacies by directing their current pharmacy to do so; inputting prescription information directly to the website; and Internet sellers' allowing consumers to use prescriptions that have previously been filled online. *See id.*

[33] *See* David Hasemyer, *An Internet Prescription for Disaster?*, SignOnSanDiego.com, Dec. 20, 2003, http://www.signonsandiego.com/news/health/20031220-9999_1n20interdoc.html.

Association, the National Association of Boards of Pharmacy, and the Drug Enforcement Administration.[34]

As might be evident from a cursory assessment, the potential for fraud and inappropriate sales of drugs over the Internet is high, particularly in the latter circumstances. Any system of drug purchasing without a substantive physician-patient relationship and a valid prescription is dangerous.[35] Of course, as noted previously, many websites simply do not require a prescription at all, allowing the unfettered purchase of drug materials over the Internet.[36] Clearly, greater risk of harm is associated with transactions that result in fake or substandard materials being ingested by patients.[37]

Some online drug sellers have responded to this risk by specifically disclaiming liability for the prescription drugs they mail to customers.[38] Some government policymakers have adopted a similar strategy. State government drug importation sites such as those in Washington, Minnesota, and Illinois have attempted to distance themselves from liability of potentially poor quality or counterfeit drugs in their online drug importation programs by requiring citizens to agree to "hold-harmless provisions" before they can access these state-sanctioned websites.[39]

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[34] *See* NATIONAL CENTER ON ADDICTION AND SUBSTANCE ABUSE AT COLUMBIA UNIVERSITY, *supra* note 6, at 3-4.

[35] *See id.* (describing deaths and addictions due to Internet cyberdoctor prescribing); Ma, *supra* note 16 and accompanying text.

[36] *See infra* notes 58-62 and accompanying text (discussing web sites that allow for purchase without a valid prescription); *see also* NATIONAL CENTER ON ADDICTION AND SUBSTANCE ABUSE AT COLUMBIA UNIVERSITY, *supra* note 6, at 3-4 (indicating that most online sellers of controlled prescription drugs do not to require a prescription); Ma, *supra* note 16 and accompanying text.

[37] *See* Fung et al., *supra* note 4, at 190; Ma, *supra* note 16.

[38] *See* Sana Siwolop, *Personal Business; Buying Your Pills Online May Save You Money, But Who's Selling Them?*, N.Y. TIMES, Sept. 29, 2002, *available at* 2002 WLNR 4032486.

[39] *See* Liang, *supra* note 2, at 311. The debate on drug importation as a strategy to address access to drugs is beyond the scope of this article; instead, the focus here is the risks of unregulated drug sales, particularly to vulnerable patient populations. However, interested readers may wish to review (on the pro-importation side) articles such as: Tim Gilbert & Sana Halwani, *Confusion and Contradiction: Untangling Drug Importation and Counterfeit Drugs*, 36 CAL. W. INT'L L.J. 41 (2005) (arguing that banning Canadian importation will not eliminate issues of counterfeit drugs in the U.S.); Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193 (2005) (arguing some forms of pharmaceutical arbitrage through importation and cross-border purchasing are beneficial and do not adversely impact innovation, and that the threat of pharmaceutical arbitrage is overstated); Kevin Outterson & Ryan Smith, *Counterfeit Drugs: The Good, the Bad, and the Ugly*, 16 ALB. L.J. SCI. & TECH. 525, 537 (2006) (arguing that "conflating criminal placebos with importation . . . only serves the interest of drug company profits rather than a serious discussion of public health"); Andy Troszok, *Reimportation from Canada and Beyond*, 36 CAL. W. INT'L L.J. 55, 55 (2005) (arguing Canadian importation is safe and those criticizing importation are "fear mongering"); Michael Moreno, *Prescription Drug Importation Beyond Canada*, 36 CAL. W. INT'L L.J. 125 (2005) (supporting drug importation from Canada).

The articles above may be contrasted with (on the con side of importation): William P. Bro, *Importation of Prescription Drugs and Risks to Patient Safety*, 36 CAL. W. INT'L L.J. 105 (2005) (indicating from a patient's perspective that importation would result in increased risks to consumers); Robert P. Giacolone, *Drug Wholesaling and Importation: Challenges and Opportunities*, 36 CAL. W. INT'L L.J. 65 (2005) (noting that from a wholesaler's perspective, infusion of imported drugs into the U.S. supply chain may undermine integrity of the supply chain); Daniel Gilman, *Oy Canada! Trade's Non-Solution to "The Problem" of U.S. Drug Prices*,

III. LIMITED SEARCH ENGINE OVERSIGHT

The lack of any oversight by search engines exacerbates the risk of purchasing drugs online. This practice is particularly objectionable as both the search engines and the drug sellers obtain major financial benefits from illicit drug sales.

A. Search Engine Profits

All major search engines, including Google, Yahoo, and Microsoft, receive profits through web page advertisements. Generally, websites selling products or services relating to search results are listed on a main page.

In addition, a list of sponsored links that are customized to the search terms entered usually appears either above the search results or in the right

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32 Am. J.L. & Med. 247 (2006) (arguing drug reimportation will not address U.S. drug pricing issues due to regulatory challenges across borders); Aidan Hollis & Peter Ibbott, *How Parallel Trade Affects Drug Policies and Prices in Canada and the United States*, 32 Am. J.L. & Med. 193 (2006) (drug importation from Canada unlikely to substantively benefit U.S. and may harm Canada); Mary Ellen Fleck Kleiman, *State Regulation of Canadian Pharmacies: A Prescription to Violate the Supremacy Clause*, 32 Am. J.L. & Med. 219 (2006) (arguing state-based drug importation programs violate Supremacy Clause of the U.S. Constitution); Edward L. Langston, *The Quality Quandary*, 36 Cal. W. Int'l L.J. 19 (2005) (discussing misunderstanding of regulatory safety for Canadian imported drugs); Liang, *supra* note 2 (arguing drug importation not an appropriate policy alternative due to challenges in drug supply vulnerability and international regulatory regimes); Liang, *supra* note 3 (arguing strategies such as drug importation and technology-based supply chain safety efforts are both failed policy efforts to promote appropriate access to pharmaceuticals for vulnerable patient populations); Bryan A. Liang, *Structurally Sophisticated or Lamentably Limited? Mechanisms to Ensure Safety of the Medicine Supply*, 16 Alb. L. J. Sci. & Tech. 483 (2006) (reviewing technology to track and detect suspect drugs and concluding they are inadequate for ensuring safety of the vast U.S. drug supply); Bryan A. Liang, *Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into the Public's Health*, 31 N.C. J. Int'l L. & Com. Reg. 847 (2006) (discussing risks of importation due to challenges with safety of parallel trade in countries from which the U.S. would import drugs); Bryan A. Liang, *Over the Virtual and Geographic Borders: Understanding Importation and Counterfeit Drugs*, 36 Cal. W. Int'l L.J. 7 (2005) (warning that unfettered importation may put patients at risk for substandard and counterfeit drugs); Ma, *supra* note 16, at 371 ("Reimportation has surfaced in the last few years as a possible remedy for the prescription drug price situation in the United States, but has been criticized for putting consumer heath and safety at risk and negatively impacting research and development efforts."); Jared Martin, *United States Prescription Drug Crisis: Reimportation of Canadian Prescription Drugs Is Not the Answer*, 27 J. Legal Med. 477, 489-90 (2006) ("Canada's proposed ban on the reimportation of prescription drugs should send a strong message to the United States that its citizens can no longer depend on obtaining their prescription drugs from the less expensive Canadian market."); Rene F. Rodriguez, *Drug Importation and the Hispanic Physician*, 36 Cal. W. Int'l L.J. 117, 124 (2005) (arguing that alternative drug programs, such as drug importation, create a two-tier system that puts the brunt of policy risk upon the poor); Marv Shepherd, *Drug Quality, Safety Issues and Threats of Drug Importation*, 36 Cal. W. Int'l L.J. 77 (2005) (noting that current state of understanding of risks of imported drugs indicates importation not appropriate policy answer to drug access); Devlin Taylor, *Importing a Headache for which There's No Medicine: Why Drug Reimportation Should and Will Fail*, 15 J.L. & Pol'y 1421, 1446 (2007) ("[A]n increase in insurance costs could potentially mitigate any savings a comprehensive drug reimportation plan would bear."); Adam T. Teufel, *Legalized Importation of of Canadian Prescription Drugs: Short-Term Solution to a Long-Term Problem*, 22 J. Contemp. Health L. & Pol'y 383 (2006) (arguing Congress should not jeopardize drug safety and efficacy by legalizing importation); John A. Vernon et al., *The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate*, 32 Am. J.L. & Med. 175 (2006) (under an economic analysis, reimportation will not achieve costs savings for U.S. consumers).

hand margin. Search engines sell or auction spots on this list, which dictates the particular positioning of the sponsored link on this list when that keyword is searched.[40] Each time a user clicks through the search engine sponsored advertisement, the search engine is paid.[41] Hence, search engines are focused on having as many advertisers as possible pay for positioning on the search engine's website.

B. Internet Drug Sales

With respect to Internet drug sales, the major search engines "require" that any of their advertisers who sell prescription drugs be approved through the PharmacyChecker.com verification program. The verification theoretically requires a valid pharmacy license in U.S. or Canada, as well as correct contact information of the seller on the website and security of purchaser information.[42]

Unfortunately, the PharmacyChecker.com verification program allows for foreign and suspect online sellers to advertise on these primary search engines with virtual impunity. Compared with the National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Site ("VIPPS") program, which is a rigorous evaluation system of pharmacies that use the Internet, is focused on drug safety and legitimacy, and has accredited only fifteen pharmacies,[43] PharmacyChecker.com has much less stringent requirements and has certified hundreds of online drug sellers.[44]

The ease with which online drug sellers can be PharmacyChecker.com verified is disturbing, and the implications are frightening. All of the major search engines require a website to be based in Canada or the U.S. before verification, yet, there is no way to ascertain the true locale of the drug seller.[45]

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[40] *See* Rick Carr, *Search Engine Wars: Making Money Off Search* (National Public Radio broadcast Apr. 14, 2004), http://www.npr.org/templates/story/story.php?storyId=1836736. Note that Google, Yahoo, and MSN represent virtually the entire search engine market, with almost 90% of ad server market share. *See, e.g.*, Get Your Fair Share of the Ad Network Pie, http://www.attributor.com/blog/get-your-fair-share-of-the-ad-network-pie/ (Mar. 30, 2008).

[41] *See* Carr, *supra* note 40.

[42] *See* Google's Online Pharmacy Qualification Process, http://www.google.com/adwords/pharmacy_qualification.html (last visited Feb. 1, 2009); Microsoft Advertising Editorial Guidelines, http://advertising.microsoft.com/Home/Article.aspx?pageid=&Adv_ArticleID=3211 (last visited Feb. 1, 2009); PharmacyChecker.com Verification Program, http://www.pharmacychecker.com/sealprogram/choose.asp (last visited Feb. 1, 2009); Yahoo Search Marketing Pharmacy Certification Program, http://searchmarketing.yahoo.com/legal/rx.php (last visited Feb. 1, 2009).

[43] VIPPS is a much more rigorous system focused on safety. The VIPPS program requires a pharmacy to comply with: (i) licensing and inspection requirements of their home state; (ii) licensing and inspection requirements of each state to which they dispense pharmaceuticals; (iii)verification of valid prescriptions from licensed physicians; and (iv) NABP VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. *See* National Association of Boards of Pharmacy – Verified Internet Pharmacy Practice Sites (VIPPS), http://www.nabp.net/index.html?target=/vipps/intro.asp& (last visited Feb. 1, 2009).

[44] *See* PharmacyChecker.com – Price Comparisons, http://www.pharmacychecker.com/ListingAlpha.asp (last visited Feb. 1, 2009).

[45] *See* websites cited *supra* note 42.

International online drug sellers can therefore access U.S. patients and markets by claiming a Canadian locale. Even assuming that these websites are telling the truth about where they are located, such a claim does nothing to ensure safety. In general, domestic safety laws do not apply if drugs are not for domestic consumption.[46] For example, counterfeit or tainted drug products from China and India slated for U.S. citizens via Canadian-based online sales are unregulated by Health Canada because they are not intended for Canadian citizens: "Canadian law does not require the country to regulate or guarantee the safety of prescription medicines manufactured in foreign nations and transshipped through Canada to the United States."[47] Indeed, online Canadian pharmacies have been found to sell unapproved drugs from Mexico to U.S. citizens.[48] The sourcing of pharmaceuticals in Canada from highly suspect countries has grown alarmingly.[49] Drugs from these countries are primarily for export because they do not fulfill current Good Manufacturing Practices in Canada and therefore cannot be sold to Canadian citizens.[50]

C. An Illustration: RxNorth.com

The case of RxNorth.com illustrates the dangers of relying on PharmacyChecker.com verification. RxNorth.com was a PharmacyChecker.com verified pharmacy and the largest Canadian Internet drug seller. It was caught selling fake drugs to U.S. citizens.

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[46] *See* Liang, *supra* note 2, at 297.

[47] Press Release, Partnership for Safe Medicines, Sharp Increase in Foreign Prescription Drugs Entering Canada, (Apr. 6, 2004), http://www.accessmylibrary.com/coms2/summary_0286-20927552_ITM?email=bliang@cwsl.edu&library. Note that even these countries' legitimate supply chain is suspect. *See, e.g.*, John R. Wilke, *Ranbaxy Probe Extends to Africa Drugs*, Wall St. J., July 15, 2008, *available at* http://www.aegis.com/news/wsj/2008/WJ080703.html (reporting Ranbaxy, India's largest drug company, under FDA and Department of Justice investigation for manufacturing substandard generic drugs, pattern of systemic fraudulent conduct, and fabrication of documents to cover up substandard products; and reporting that 2006 investigation of Ranbaxy found quality problems with Ranbaxy plant in India).

[48] *See* Liang, *supra* note 2, at 297.

[49] There has been a tremendous increase in imported drugs into Canada from questionable sources, including "significant increases in Canadian imports of pharmaceuticals from Singapore (30%), Ecuador (198%), China (43%), Iran (2,753%), Argentina (221%), South Africa (84%) and Thailand (52%) between September 2002 and September 2003." *See* Partnership for Safe Medicines, *supra* note 47. This global sourcing also extends increasingly to generic forms of drugs. *See, e.g.*, Gardiner Harris, *Drug Making's Move Abroad Stirs Concerns*, N.Y. Times, Jan. 23, 2009, *available at* http://www.nytimes.com/2009/01/20/health/policy/20drug.html (noting the increase in generic drug manufacturing overseas creates safety risks); *see also* Bryan A. Liang, *Pigs, Drugs, and Terrorists*, Patient Safety & Quality Healthcare, Nov.-Dec. 2008, at 10-12 (describing risks of globalization of drug supply). It should be noted that generic drugs are, worldwide, the most frequently counterfeited set of drugs. *See* Julian Harris & Philip Stevens, *Fake Drugs and Failed Governance*, China Post, Jan. 16, 2009, *available at* http://www.chinapost.com.tw/commentary/the-china-post/special-to-the-china-post/2009/01/16/192286/p1/Fake-drugs.htm (noting generics are the most consumed drug type and calling for greater governance to promote access to medicines).

[50] *See id.*

RxNorth.com was investigated after a whistleblower told a Canadian news program that the drugs RxNorth.com sold were not from Canada and were being shipped from the Bahamas.[51] Upon further detailed investigation, this was verified.[52] There were also allegations of concealed expiration dates, drugs sold near expiration, and poor quality.[53]

Although the deceptive practices were of great concern, the situation was even more problematic than appeared at first blush. In what was thought to be an unrelated investigation, U.K. authorities intercepted a four pallet shipment of pharmaceuticals from the United Arab Emirates that included "products" made by eight drug companies that were all, in fact, counterfeit. These drugs' intended recipient was Personal Touch Pharmacy, in the Bahamas. However, in a chance and chilling revelation, investigators discovered that Personal Touch Pharmacy was partnered with or the same as RxNorth.com—in fact, their computers were linked.[54]

Authorities discovered that the counterfeiting effort was extensive and sophisticated. Beyond the far-reaching international distribution system, the blister packaging of the products to be sold by Personal Touch Pharmacy/RxNorth.com was virtually identical to the authentic product.[55] Further, the fake drugs used a legitimate product lot number.[56] Upon being notified of these counterfeits, Bahamian authorities raided the Bahamian warehouse and found $3.7 million worth of products, spanning thirteen different manufacturers, constituting 3.025 million dosage units.[57] The Bahamian investigation indicated that Personal Touch Pharmacy and its links with RxNorth.com had annual sales of approximately $8 million.[58]

The international counterfeiting system employed by RxNorth.com illustrates a whitewashing mechanism used to disguise the sourcing of counterfeit drugs. A *New York Times* investigation found that the shipments used a sophisticated means of Free Trade Zones such as Dubai to shift illicit drug products that ultimately originated from China and were being sent through the U.K. to the Bahamas, and then back to the U.K. to hide their origins and promote the perception of legitimacy of the drugs.[59] It also

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[51] *See* Kathy Tomlinson, *Ex-worker Blows Whistle on Popular Web Pharmacy*, CTV.CA, May 26, 2006, http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20060510/whistleblower_internetdrugs_060525/20060525/ (reporting on Edward Hector, a whistleblower who outlined practice of using Bahamas facility to dispense Rx North drugs not from Canada and other problematic business practices including drugs shipped that were near expiration or with expiration dates concealed).

[52] *See Assessing the Safety of Our Nation's Drug Supply: Hearing Before Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 4-5 (2007) (testimony of John Theriault, Chief Security Officer and Vice President, Global Security, Pfizer Inc.), *available at* http://energycommerce.house.gov/cmte_mtgs/110-he-hrg.050907.Theriault-testimony.pdf) [hereinafter Testimony of John Theriault].

[53] *See* Tomlinson, *supra* note 51.

[54] *See* Testimony of John Theriault, *supra note* 52, at 4-5.

[55] *See id.* at 5.

[56] *See id.*

[57] *See id.*

[58] *See id.*

[59] *See* Walt Bogdanich, *A Toxic Pipeline: Counterfeit Drugs' Path Eased by Free Trade Zones*, N.Y. TIMES, Dec. 17, 2007, *available at* http://www.nytimes.com/2007/12/17/world/middleeast/17freezone.html?ex=1198558800&en

reported that the United States Food and Drug Administration ("FDA") investigation into RxNorth.com resulted in a warning against purchasing from the online seller because of the high risk of counterfeits.[60]

Furthermore, the *New York Times* noted that RxNorth.com had been disciplined in 2001 by the Manitoba Pharmaceutical Association for filling more than 10,000 medication orders from U.S. patients without a valid prescription.[61] Despite this warning, RxNorth.com continued to be a PharmacyChecker.com verified pharmacy—with the highest PharmacyChecker.com rating of five checkmarks.[62] The CEO of RxNorth.com closed down operations as of January 31, 2008, transferring them to CanadaDrugs.com—another PharmacyChecker.com verified drug seller.[63]

D. Unenforced "Requirements"

Beyond the fact that PharmacyChecker.com has "verified" suspect online drug sellers, allowing them to market drugs through search engine advertisements that purportedly fulfill its requirements, the search engines themselves allow sales by online sellers that in fact do not fulfill PharmacyChecker.com's requirements. As discussed above, RxNorth.com, like many other "verified" online drug sellers, dispensed medications without valid prescriptions. Even worse, other "verified" sellers are also touting addictive, Schedule II controlled substances such as morphine derivatives without a prescription.[64]

Unfortunately, over the Internet, such illicit drug sales are not the exception. As noted above, studies have revealed the large number of online drug sales that do not require a prescription.[65] Analysis of these websites also

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=2f54219f6ae8d265&ei=5070&emc=eta1; *see also* Patsy Moy, *HK at Center of Global Drugs Scam*, The Standard (H.K.), Feb. 11, 2008, *available at* http://www.thestandard.com.hk/news_detail.asp?pp_cat=12&art_id=61319&sid=17539318&con_type=1 (discussing Hong Kong as transshipment port for China counterfeit drugs and its status as a "free port"); and P. B. Jayakumar, *Asian Nations Unite against Spurious Drugs*, Business Standard (India), Feb. 12, 2008, *available at* http://www.business-standard.com/common/news_article.php?leftnm=lmnu4&subLeft=5&autono=313403&tab=r (discussing industry, government customs, and Interpol program on counterfeits and reporting that only 5% of medicines inspected at free trade ports).

[60] *See* Bogdanich, *supra* note 59.

[61] *See id.*

[62] *See* Many Rx Web Sites Lack Proper Licensing: Analysis, http://gulfmd.com/Drug%20Info/ManyRxWebSitesLackProperLicensing.asp?id=9 (last visited Feb. 1, 2009).

[63] *See* Bogdanich, *supra* note 59; CanadaDrugs.com Is Proud to Serve Rx North Customers, http://www.canadadrugs.com/rxnorth/index.php?REF=Redirect/keyword=rxnorth.com (last visited Feb. 1, 2009).

[64] *See, e.g.*, LegalMedsDirect.com, http://www.legalmedsdirect.com (last visited Feb. 1, 2009) (which allows patients to purchase controlled substances such as Oxycodone without a prescription (search done June 20, 2008)). Many sponsored websites come up when searching "Oxycodone without prescription" or "Oxycodone no prescription."

[65] *See supra* notes 6-7 and accompanying text (describing large percentage of drug sellers online that do not require a valid prescription); *see also* Press Release, Drugs.com, MarkMonitor Brandjacking Index Exposes Online Scams That Threaten Top Pharmaceutical Brands and Hurt Consumers (Aug. 20, 2007), http://www.drugs.com/news/markmonitor-brandjacking-index-exposes-online-scams-threaten-top-pharmaceutical-brands-hurt-

indicated that greater than fifty percent of them did not secure customer data, in direct violation of PharmacyChecker.com requirements.[66] This places buyers at risk for identity theft.

Other weaknesses attend the current PharmacyChecker.com/search engine accountability system. Online drug sellers verified by PharmacyChecker.com are not merely Canadian or domestic, as required by PharmacyChecker.com requirements. Indeed, they are listed to be in a wide array of countries, including Barbados, the U.K., New Zealand, Israel, India, Mexico, Vanuatu, Australia, as well as other countries not listed because PharmacyChecker.com does not provide a complete list of all online drug sellers its verifies.[67] This result is consistent with an FDA-commissioned study that found that of 11,000 purportedly "Canadian" websites, only 214 were actually registered to a Canadian entity.[68] Other websites selling pharmaceuticals that claim Canadian sourcing are located in Malaysia, Vanuatu, Eastern Europe, and elsewhere.[69]

Further, PharmacyChecker.com verification permits the dangerous practice of online drug sellers simply using an "online consultation" as the basis for prescription sales. For example, KwikMed.com, a verified PharmacyChecker.com site has been sued by the Arkansas Attorney General over this practice, yet the online seller still remains "verified."[70]

E. No Verification

It should be noted that beyond poor accountability for fulfilling PharmacyChecker.com "requirements," search engines also allow non-PharmacyChecker.com verified drug sellers to advertise as well. A whole host of drug seller websites advertise on Yahoo, Google, and MSN without any

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6716.html (demonstrating that of greater than 3,000 Internet drug seller sites most visited, 10% openly indicated that no prescription was necessary for drug purchases).

[66] *See id.*

[67] *See* Pharmacy Ratings and Profiles, http://www.pharmacychecker.com/OnlinePharmacyRatings.asp (last visited Feb. 1, 2009).

[68] *See* Ricardo Alonso-Zaldivar, *FDA Casts Suspicion on Online Pharmacies*, Seattle Times, June 15, 2005, at ¶ 3, *available at* http://seattletimes.nwsource.com/html/nationworld/2002336462_fda15.html. Countries to which the web sites were registered included the United States, Vietnam, the Czech Republic, and Barbados. *Id.* at ¶ 4; *see also* David Work, *Phony Medicines Available Online: Bogus Pharmacies on Internet Spread Drugs that Can Be Dangerous, Deadly*, Winston-Salem J., Feb. 16, 2009, *available at* http://www2.journalnow.com/content/2009/feb/07/phony-medicines-available-online/opinion/ (discussing extensive nature of fake drugs and how a website with listed Canadian location forwarded drug orders to Israel and then financial information to Russia where the credit card transaction was processed; the pharmaceutical was shipped from India to a consumer in the United States); G. Jackson, *Faking It: The Dangers of Counterfeit Medicine on the Internet*, 63 Int'l J. Clin. Prac. 181 (2009) (describing another Canadian website operating a drug selling scheme that on inspection had its domain name hosted Korea, registered in St. Kitts, with orders dispatched from Oklahoma City).

[69] *See* Liang, *supra* note 2, at 310; *see also* Press Release, U.S. Food and Drug Administration, FDA Says Consumers Continue to Buy Risky Drugs Online ¶ 4 (Nov. 1, 2007), http://www.fda.gov/bbs/topics/NEWS/2007/NEW01735.html (describing Operation Bait and Switch, where FDA officials that only 15% of drugs claimed to be of Canadian origin actually originated there).

[70] *See* Associated Press, *State Sues Web Pharmacy on Slack Rules*, NWANews.com, Dec. 12, 2007, *available at* http://www.nwanews.com/adg/News/210398.

"verification" at all.[71] Indeed, many of these websites are "affiliate" or mirror" sites—in other words, they are duplicate websites used to garner a larger web presence.[72] These mirror or affiliate sites generally divert traffic back to the original site and obtain a commission for doing so.[73]

In summary, search engines exert very little effort to ensure that online drug sellers from which they obtain advertisement revenue are legitimate. Yet the unregulated nature of Internet drug sales creates tremendous challenges for oversight. As a result, suspect drug products enjoy continuing sales without any oversight at all.[74] Given the vast number of online drug sellers, in combination with the total lack of accountability for search engine-sponsored sales, the scope of illicit online drug sales is large, extensive, and entirely unregulated.

IV. INTERNATIONAL AND DOMESTIC EFFORTS

Internet drug sellers pose a serious global health concern that has generated both international and domestic attention. International health organizations and governments have issued guidance to help provide consumers with important information regarding the risks involved with purchasing medications online. The effectiveness of such communications, however, is questionable.

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[71] *See, e.g.*, drugstorescripts.com, scriptsatdiscount.com, atcostpharma.com, bestmedvalues.com, emedsaver.com, disountprescriptionmedications.com, rxpop.com, buymedsquick.com, and others. This search and analysis was performed on June 20, 2008; of course, the nature of the Internet allows these websites to come and go with little detection. Unfortunately, this lack of verification simply reflects the limited or non-existent accountability of search engines generally. *See, e.g.*, Oren Bracha & Frank Pasquale, *Federal Search Commission? Access, Fairness, and Accountability in the Law of Search*, 93 CORNELL L. REV. 1149 (2008) (calling for regulation of search engines due to oligopoly of search engines dominating market); Frank Pasquale, *Asterisk Revisited: Debating a Right of Reply on Search Results*, 3 J. BUS. & TECH. L. 61 (2008) (outlining proposal to allow right of reply to ameliorate potential search engine results that are damaging or inaccurate); Frank Pasquale, *Rankings, Reductionism, and Responsibility*, 54 CLEV. ST. L. REV. 115, 117 (2006) ("[S]ome accountability for search engine results is increasingly necessary as they become the primary portal for net users.").

[72] Scott Carr & Michael Bluett, *Spotting Mirrors, Affiliates, and Similar Sites*, DMOZ MONTHLY, http://www.dmoz.org/newsletter/2001Sep/spam.html.

[73] *See id.*; for an example of how this system works, *see* imaté Affiliate Program, http://www.imate.com.au/affiliate_app.html (last visited Feb. 1, 2009).

[74] *See Internet Drug Sales: Hearing Before the H.R. Comm. on Government Reform*, 108th Cong. (2004) (statement of William K. Hubbard, Associate Commissioner for Policy and Planning and Legislation, U.S. Food and Drug Administration), *available at* http://www.fda.gov/ola/2004/Internetdrugs0318.html; Andy Greenberg, *Brandjacking Big Pharma*, FORBES.COM, Aug. 20, 2007, *available at* http://www.forbes.com/technology/2007/08/20/brandjacking-drugs-pharmaceuticals-tech-cx_ag_0820brand.html (describing challenges to public and private online sales); Buying Medicines over the Internet: MHRA, http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/BuyingmedicinesovertheInternet/CON019610 (last visited Feb. 6, 2009) (describing jurisdiction and accountability issues for online sales of drugs).

A. World Health Organization

The World Health Organization ("WHO") has recognized the dangers posed by Internet drug sellers. Its particular concern is that these Internet drug sales bypass national drug regulatory authorities, thus allowing the entry of medical products into the global marketplace that may be unapproved, fraudulent, unsafe, or ineffective.[75]

As early as 1997, WHO specifically called on its member states to "tighten controls on the sale of medical products through the Internet."[76] More recently, in response to this growing concern, WHO has collected information on various aspects and consequences of Internet sales of medical products and worked with international drug regulatory authorities, national and international enforcement agencies, consumer groups, professional associations, and the pharmaceutical industry to convene a working group to address this issue.[77] Included within this effort were surveys of drug regulatory efforts to address Internet drug sales. Results from these surveys were not encouraging, with only five countries reporting specific regulation of Internet pharmacies at that time.[78]

WHO has taken a number of steps to assist drug regulatory and other authorities to control illicit online drug sellers. These include: (1) developing a guide on medical products and the Internet available in several languages for members states to use as a model to adopt locally; (2) developing a draft Model Web Site for drug regulatory authorities to improve access to regulatory information; (3) working with the World Intellectual Property Organization ("WIPO") to control the use of international nonproprietary names of drugs and domain names on the Internet often connected with illegal sites; and (4) soliciting information from member states to assess how members regulate the promotion and sale of pharmaceuticals over the Internet and how they control the export of drugs.[79]

Despite these efforts, dangerous online drug sales continue to proliferate. Recent data from WHO estimates that up to fifty percent of drugs sold online are fake.[80] As mentioned earlier, some websites claim sourcing from and

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[75] *See* World Health Organization, *WHO Drug Information*, 15 World Drug Info. 146, 149 (2001), *available at* http://www.who.int/medicinedocs/en/d/Jh2989e/#Jh2989e.2.1.

[76] *See id.* at 149.

[77] *See* World Health Organization, Pharmaceuticals and the Internet: Drug Regulatory Authorities' Perspective (2001), http://whqlibdoc.who.int/hq/2001/a74987.pdf.

[78] *See id.* at 8.

[79] *See id.* at 7-8. In addition, as part of the international concern regarding safety of drugs being sold in nontraditional sectors, the Organization of Economic and Community Development and WIPO have also convened meetings; *see, e.g.*, Bryan A. Liang, Presentation at the Joint Meeting of the Organization of Economic and Community Development and the World Intellectual Property Organization (Oct. 18, 2005) (discussing the social and economic costs on intellectual property in the broader context of counterfeit products); OECD and WIPO, Counterfeiting and Piracy, Expert Meeting on Measurement and Statistical Issues, Organization of Economic and Community Development and World International Property Organization, Geneva, Switzerland, October 17-18, 2005 (discussing means to track and investigate suspect drug epidemiology); OECD, The Economic Impact of Counterfeiting and Piracy, Part I: Overall Assessment DRAFT (2007), http://www.oecd.org/dataoecd/36/36/39543399.pdf.

[80] *See* WHO and Partners Accelerate Fight against Counterfeit Medicines, http://www.who.int/mediacentre/news/releases/2006/pr69/en/index.html (last visited Feb. 1,

presence in "trusted" countries such as the U.K. and Canada or other industrialized countries, implying that because their businesses/drugs originate in that country, they are safe. In actuality, these drugs are illegally manufactured in poorer countries where health and safety regulation is less stringent and the potential for substandard drugs and counterfeit is much higher.[81]

This is not simply an issue for developing countries, however. For example, one of the largest fake Viagra scams was uncovered in the U.K., with counterfeits from China, India, and Pakistan being sold over the Internet to consumers in the U.S., U.K., Canada, and other developed countries.[82]

Further, a recent European analysis of Internet online sellers has reported additional worrisome results.[83] These include findings that 93.8% of online sellers have no verifiable pharmacist available for consultation, 90.3% of these sellers simply do not require a prescription before sale of products to purchasers,[84] 80.3% have no verifiable bricks-and-mortar address, 95.6% are *not* licensed by a board of pharmacy or other appropriate listing,[85] and, 50% did not include any patient information leaflets.[86] These results spanned drug purchases of "lifestyle" drugs such as erectile dysfunction drugs, as well as cardiovascular, respiratory, mental health, Alzheimer's, and other drugs.[87]

2009). When there is no physical address associated or listed with the website, WHO estimates that *greater than* 50% of drugs sold from these sources are fake. *See* Counterfeit Medicines, http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html (last visited Feb. 1, 2009); *see also* Press Release, International Medical Products Anti-Counterfeiting Taskforce, Counterfeit Medicines: An Update on Estimates (Nov. 15, 2006), http://www.dangerouspill.com/assets/files/TheNewEstimatesCounterfeit.pdf .

[81] *See* Liang, *supra* note 2, at 296.

[82] *See Gang Guilty of Fake Viagra Scam*, BBC NEWS, Sept. 17, 2007, http://news.bbc.co.uk/2/hi/uk_news/6999160.stm.

[83] EUROPEAN ALLIANCE FOR ACCESS TO SAFE MEDICINES, THE COUNTERFEITING SUPERHIGHWAY (2008), http://v35.pixelcms.com/ams/assets/312296678531/455_EAASM_counterfeiting%20report_020608.pdf.

[84] *See id.* at 19.

[85] *See id.* at 20.

[86] *See id.* at 28.

[87] *See id.* at 22. Note also that the U.K. authorities have indicated that other drugs seized from online sellers included counterfeit heart attack and cancer treatment. *See Men Warned over Counterfeit Drugs*, BBC NEWS, Nov. 12, 2008, *available at* http://news.bbc.co.uk/2/hi/health/7721789.stm. It has been estimated that counterfeiting gangs in China are manufacturing fakes with an estimated 8 million counterfeit pills reaching the National Health Service patients. *See* Mark Townsend, *Health Fears Grow as Fake Drugs Flood into Britain*, OBSERVER (UK), Jan. 4, 2009, *available at* http://www.guardian.co.uk/business/2009/jan/04/fake-pharmaceuticals-drugs-china-nhs (describing fake anti-psychotic drug made in China, labeled in French, shipped to Singapore, and ending up in Liverpool and sold in the UK National Health Service); Paul Burnell, *How Fake Drugs Got into the NHS*, BBC NEWS, Feb. 3, 2009, *available at* http://news.bbc.co.uk/2/hi/health/7865569.stm (describing UK Medicines Health products Regulatory Agency emergency recall notices to recoup thousands of packages of fake drugs for stroke patients, prostate cancer victims, and schizophrenics); Andrew Jack, *Drugs Watchdog Demands Tough Powers*, FIN. TIMES, Jan. 3, 2009, *available at* http://www.ft.com/cms/s/0/157863e0-d925-11dd-ab5f-000077b07658.html (reporting UK regulator requesting more powers to clamp down on UK illegal medicine sales).

In addition, another recent study found that online drug sellers are rapidly increasing their business.[88] From 2007 to 2008, it appears that the same online users now visit online drug sellers at triple the rate.[89] Yet only two of the 3,000 or so online drug sellers were certified by the National Association of Boards of Pharmacy as trusted sites, with "discounts" as great as eighty-five percent—strongly suggesting counterfeits.[90]

The National Association of Boards of Pharmacy released findings in October 2008 that reported more dismal news. It found that ninety-seven percent of Internet drug sellers are operating outside of state and federal laws as well as patient safety and pharmacy practice standards.[91] Concerns with these sites include not requiring a valid prescription, not securing patients' personal information, and selling unapproved foreign drugs.[92]

WHO has attempted to involve the international community in addressing the problem. For example, WHO coordination with international drug regulatory agencies via the International Committee of Drug Regulatory Agencies ("ICDRA") aims to improve measures of protecting international public health through enhancing active collaboration among national agencies and emphasizing public education of consumers with respect to risks of online purchasing.[93] WHO has also specifically addressed the danger of Internet drug sellers and their distribution of counterfeit drugs more broadly through the WHO International Medical Products Anti-Counterfeiting Taskforce ("IMPACT"). IMPACT is an international industry-government-NGO effort to address the safety of the drug supply.[94]

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[88] *See* Andy Greenberg, *The Drug Business: Pharma's Black Market Boom*, FORBES.COM, Aug. 26, 2008, *available at* http://www.forbes.com/2008/08/25/online-pharma-scams-tech-security-cx_ag_0826drugscam.html (noting that the online drug selling "business seems to be booming").

[89] *See id.*

[90] *See id.*

[91] *See* National Association of Boards of Pharmacy, *NAPB Findings Underscore Dangers of Purchasing Prescription Medicine Online and From Foreign Sources*, INT'L BUS. TIMES, Oct. 23, 2008, *available at* http://www.ibtimes.com/prnews/20081023/napb-web-meds-safety.htm.

[92] *See id.*

[93] Justina A. Molzon, *Drug Promotion and Sales through the Internet*, *in* 10TH INTERNATIONAL CONFERENCE OF DRUG REGULATORY AUTHORITIES 117-19 (2002), http://www.who.int/medicinedocs/collect/medicinedocs/pdf/s4923e/s4923e.pdf.

[94] International Medical Products Anti-Counterfeiting Taskforce, http://www.who.int/impact/en/ (last visited Feb. 3, 2009). IMPACT includes members from groups such as Interpol, Organization for Economic Co-operation and Development, World Customs Organization, World Intellectual Property Organization, World Trade Organization, International Federation of Pharmaceutical and Manufacturers' Associations, International Generic Pharmaceuticals Alliance, World Self-medication Industry, Asociacion Latino Americana de Industrias Farmaceuticas, World Bank, European Commission, Council of Europe, Commonwealth Secretariat, ASEAN Secretariat, International Federation of Pharmaceutical Wholesalers, European Association of Pharmaceutical Full-line Wholesalers, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, and Pharmaciens sans frontiers. *See* WHO IMPACT Frequently Asked Questions, http://www.who.int/impact/impact_q-a/en/index.html (last visited Feb. 3, 2009). Note that IMPACT should not be confused with ACTA, or the Anti-Counterfeiting Trade Agreement efforts. ACTA is a proposed multi-country, voluntary trade agreement that would attempt to address the world-wide presence of counterfeit goods by strengthening intellectual property rights enforcement and, as well, implement Internet restrictions on counterfeit goods sales. *See, e.g.*, New

Although WHO's efforts are significant, they are relatively new and early in their development.[95] Meanwhile, online drug sales continue to proliferate. The Pharmaceutical Security Institute, a nonprofit group that represents the pharmaceutical companies' corporate security directors, indicated that global seizures of tainted drugs rose twenty-four percent in 2007 from the previous year "as criminals capitalize on the growing use of the Internet."[96] Clearly, other efforts must work in concert with WHO efforts to address the challenges created by global online drug sales.

B. Food and Drug Administration

1. Oversight

The United States Food and Drug Administration ("FDA") is the primary federal agency tasked with addressing the issue of online drug sales. The FDA regulates this industry through enforcement of the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Internet Drug Sales Action Plan ("IDSAP") adopted in July 1999.[97] The FDA has broad authority to regulate the practice of selling prescription drugs when the sale is done without the supervision of a licensed professional, when connected with health care fraud, and when it involves unapproved, counterfeit, adulterated, or illegal drugs.[98] The FDA's plan primarily seeks to reduce illegal Internet sales of prescription drugs by: (1) expanding enforcement efforts through increasing monitoring and criminal or civil enforcement actions; (2) partnering with other state and federal agencies and other organizations such as the National Association of Boards of Pharmacy ("NABP") and Federation of State Medical Boards to more effectively enforce federal and state laws against illegal online sales; and (3) engaging in public outreach to better inform consumers about the dangers of Internet drug sellers.[99]

Zealand Ministry of Economic Development, Anti-Counterfeiting Trade Agreement, *available at* http://www.med.govt.nz/templates/ContentTopicSummary____34357.aspx; Electronic Frontier Foundation, http://www.eff.org/issues/acta (last visited Feb. 3, 2009). There has been tremendous controversy surrounding ACTA, primarily because of negotiations that have been non-public, *see* Mike Masnick, *EU Continues to Give Bogus Reasons for Keeping ACTA Secret*, Techdirt.com, Nov. 11, 2008, http://techdirt.com/articles/20081111/0254142796.shtml, as well as privacy and search concerns, *see* Speak Out Against ACTA, http://www.fsf.org/campaigns/acta/ (last visited Feb. 3, 2009). Negotiations on this proposed multi-lateral agreement will apparently continue into 2009. *See* The Anti-Counterfeiting Trade Agreement Fact Sheet, http://trade.ec.europa.eu/doclib/docs/2008/october/tradoc_140836.11.08.pdf (last visited Feb. 3. 2009).

[95] For example, IMPACT was only formed in 2006. IMPACT – About Us, http://www.who.int/impact/about/en/ (last visited Feb. 3, 2009).

[96] Allan D. Frank, *Illegal Viagra Leads 24% Jump in Counterfeit Medicines Seizure*, Bloomberg.com, June 10, 2008, *available at* http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aoD.ehqNgFpY.

[97] *See* Fung et al., *supra* note 4, at 190.

[98] *Id.*

[99] *See* Press Release, U.S. Department of Health and Human Services, FDA Announces New Efforts to Help Curb Illegal Prescription Drug, Marketing on the Internet (July 30, 1999) http://www.fda.gov/bbs/topics/NEWS/NEW00686.html.

2. Demand and Supply Side Efforts

a. Stemming Demand

The FDA has attempted to ensure safety of online drugs by educating purchasers and thus influencing the demand side of the transaction. As early as 1999, the FDA released information on its website that provided consumers with information regarding how to safely purchase drugs over the Internet. It attempted to provide answers about the safety of buying online, including how to tell if an online pharmacy site was legitimate, and what steps should be taken prior to buying medical products online.[100]

More recently, the FDA has launched a website dedicated to the topic of "Buying Medicines and Medical Products Online" that provides consumer bulletins on recent developments and news, guidance to consumers on buying specific medical products online, a list of warning letters to online sellers regarding prohibited practices and the ability for the public to report suspected violations by online pharmacies.[101] FDA efforts have also encompassed public outreach in an attempt to inform consumers about the dangers of buying online, as well as disseminating information about compliance and enforcement actions taken by the FDA, education campaigns, public radio service announcements, various marketing campaigns, and collaborating with other federal, and state agencies, consumer groups, health care practitioner organizations and the pharmaceutical industry to help promote public awareness.[102]

Yet despite these measures, a recent survey conducted on imports by the FDA found that consumers continue to purchase drugs online for purposes of self-medication and due to cost considerations.[103] Thus, these demand-side efforts have not reached many of those who purchase online.[104]

b. Inter-Agency Efforts to Limit Supply

1. FDA and Customs and Border Protection

Part of the role of the U.S. Customs and Border Protection ("CBP") is to enforce federal laws concerning the importation of prescription medicines and other medical goods through enforcement of the FDCA. In cooperation with the FDA, this involves the detection and seizure of prescription drugs and devices that have not been approved for sale by the FDA or are adulterated or

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[100] *See* Oliver, *supra* note 5, at 99.

[101] *See* Buying Medicines and Medical Products Online, http://www.fda.gov/buyonline (last visited Feb. 1, 2009).

[102] *See id.*

[103] *See* Press Release, U.S. Food and Drug Administration, FDA Says Consumers Continue to Buy Risky Drugs Online (Nov. 1, 2007), http://www.fda.gov/bbs/topics/NEWS/2007/NEW01735.html.

[104] *See supra* notes 23-27 and accompanying text (describing consumers who believe purchasing online is safe and that if online sellers indicate drug is legitimate, that is sufficient assurance).

misbranded. It also involves prohibiting individuals other than original manufacturers from re-importing drugs back into the U.S.[105]

Given the large number of internationally-based Internet drug sellers, CBP is in many cases the first line of defense on the supply side for consumers of potentially harmful medical products. Because of the international nature of these transactions, enforcement and inspection of medical products is primarily through U.S. mail and is done in conjunction with FDA inspectors.[106]

At the outset, the FDA has attempted to address the supply side of the purchase and sale of online drugs by taking action against suspected illegally operating websites. In cooperation with CBP, it has issued "cyber" warning letters informing website owners that they may be in violation of U.S. law and that CBP may deny the entry of their mail shipments into the U.S.[107]

However, these efforts have had limited impact. Drugs from suspect online sellers continue to flow into the U.S. In a pilot program conducted by the FDA and CBP, 721 packages out of 1,908 (37%) that arrived from nineteen countries over a five-week period were detained with notices sent to the sender that the products appeared to violate the FDCA.[108]

Further, a U.S. Department of Health and Human Services report analyzing online drug sales oversight found that only 16.9 full-time FDA employees were responsible for covering all international mail facilities in the U.S. to detect imported suspect medications—in addition to their other duties.[109] Given that it has been estimated that roughly 130 million packages containing counterfeit drug products enter the U.S. each year through the U.S. mails, little if any FDA oversight is occurring with respect to online sales on this level.[110] This situation is compounded by federal regulatory requirements that forbid destruction of contraband drug products entering the U.S. via the mails without undergoing extensive and expensive processes,

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[105] *See* Buying Prescription Medicine From Internet Pharmacies, http://www.cbp.gov/xp/cgov/newsroom/alerts/alerts/foreign_medication.xml (last visited Feb. 1, 2009).

[106] *See* Michelle Meadows, *Imported Drugs Raise Safety Concerns*, FDA CONSUMER MAGAZINE, September-October 2002, *available at* http://www.fda.gov/fdac/features/2002/502_import.html.

[107] *See* Oliver, *supra* note 5, at 100. Note that in most cases when the FDA identifies a site that is illegally selling pharmaceuticals within its jurisdiction, it works with the Department of Justice (DOJ) to build evidence for future prosecution and civil or criminal enforcement action. *See* Jane E. Henney, *Cyberpharmacies and the Role of the U.S. Food and Drug Administration*, 3 J. MED. INTERNET RES. (2001), *available at* http://www.jmir.org/2001/1/e3.

[108] Meadows, *supra* note 106.

[109] *See* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES., HHS TASK FORCE ON DRUG IMPORTATION: REPORT ON PRESCRIPTION DRUG IMPORTATION 56 fig. 5.3 (2004), http://archive.hhs.gov/importtaskforce/Report1220.pdf. Note that this figure does not include other delivery mechanisms such as Federal Express, UPS, etc. *See* MARV D. SHEPHERD, IMPROVING PATIENT CARE AND MEDICATION SAFETY 8 (2004), http://www.ashp.org/s_ashp/docs/files/2004LeadershipSummary.pdf. Shepherd also indicates that there was a 1000% increase in the number of drug packages destined for U.S. customers from 2003 to 2004. *See* Marv Shepherd, *Drug Quality, Safety Issues and Threats of Drug Importation*, 36 CAL. W. INT'L L.J. 77, 79 (2005).

[110] *See* Press Release, Steve Buyer, Cracking Down on Counterfeit Prescription Drug Distribution (Apr. 22, 2008), http://www.house.gov/apps/list/press/in04_buyer/counterfit_perscription_drugs.html.

which include holding the materials and providing the addressee with the opportunity to present evidence as to the permissibility of allowing the drug to enter.[111] In most cases, it is, ironically, returned to the sender,[112] allowing for resale.[113]

Indeed, under current FDA policy, packages flagged by CBP which are not processed or inspected by the FDA by the end of each work day are simply passed on to be delivered to the addressee by the U.S. Postal Service.[114] As a result, the FDA has admitted that an estimated 9,000 to 10,000 packages containing drugs per week are not inspected.[115] This number, however, is likely to be a severe underestimate; both CBP officials and FDA inspectors rely on a shipper's description of the contents of packaging when considering an inspection:[116] "CBP and FDA officials [indicated] that there are no assurances that the shipper's description of the contents is accurate. The FDA officials at the [mail] carrier facilities . . . told us that if a package contains a prescription drug but is inaccurately described, it would not likely be inspected by FDA personnel."[117]

As might be expected, outcomes of FDA and CBP activities to stem supply of suspect drugs to consumers are not encouraging. In testimony in front of Congress, the FDA reported only 372 Internet-related criminal investigations, 150 Internet-related arrests and 92 convictions, 100 open Internet criminal investigations, 200 cyber warning letters, and a handful of injunctions,

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[111] *See* 21 U.S.C. § 381(a) (2000); 21 C.F.R. §1.94 (2008).

[112] "According to FDA investigators, in most instances, the addressee does not present evidence to support the drugs' admissibility, and the drugs are ultimately provided to CBP or the U.S. Postal Service for return to sender." *See Prescription Drugs: Enhanced Efforts and Better Agency Coordination Needed to Address Illegal Importation: Hearing Before the H. Subcomm. on Oversight and Investigations*, 109th Cong. 33 (2005) (statement of Richard M. Stana, Director, Homeland Security and Justice Issues), *available at* http://www.gao.gov/new.items/d06175t.pdf [hereinafter Statement of Richard Stana].

[113] "[W]ith the current process, packages that are returned to the sender could, in turn, be sent back by the original sender to go through the process again." *See id.* at 35.

[114] *See id.* at 21.

[115] *See id.* at 22.

[116] *See id.* at 26 n.4. Note that:

> [S]mall mail shipments [at international mail facilities] are excluded [from FDA formal foreign inspection eligibility] because they are generally of a lower value and do not reach the threshold of a formal entry. The international mail system remains an un-automated, paper-based system and packages coming through it are not routed through FDA's electronic screening system. They are off-line and virtually unevaluated for risk, unless a wary, experienced Customs official targets a package for further FDA review. However, even in those situations, FDA can review only a very small fraction of the packages targeted by Customs.

FDA Foreign Drug Inspection Program: A System at Risk: Hearing Before the H. Subcomm. on Oversight & Investigations, Comm. on Energy & Commerce, 110th Cong. (2007) (statement of Benjamin L. England, Attorney, Jones Walker), *available at* http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.110107.England-Testimony.pdf. In addition, generally any shipment with less than a $2000 value is "essentially given a free pass as an informal Customs entry." *See FDA Foreign Drug Inspection Program: A System at Risk: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 110th Cong. 11 (2007) (statement of Carl R. Nielsen, Retired Director of the Division of Import Operations and Policy, U.S. Food and Drug Administration), *available at* http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/110-oi-hrg.110107.Nielsen-Testimony.pdf.

[117] *See* Statement of Richard Stana, *supra* note 112, at 26.

seizures, product recalls and voluntary product destruction.[118] In the context of billions of dollars of sales, proliferation of Internet sales and marketing of drugs, and limited international cooperation, the FDA's efforts have been severely challenged. Indeed, "U.S. Food and Drug Administration officials say they are unable to stop the illegal flow of drugs sold on the Internet."[119]

2. FDA, CBP, and Drug Enforcement Administration

The Drug Enforcement Administration ("DEA") acts as the enforcement agency for the Department of Justice ("DOJ") concerning the dispensing and sale of controlled substances, including transactions via the Internet as promulgated in the Controlled Substances Act.[120] In a guidance document issued in April 2001, the DEA emphasized and clarified that controlled substances may only be dispensed by licensed practitioners acting in the usual course of their professional practice and requires them to be registered with the DEA, including those who sell online.[121] Further, this guidance addresses websites that dispense drugs without a prescription by providing specific requirements for ensuring that only legitimate prescriptions are written and filled, and requirements for the importation of controlled substances.[122]

These rules require Internet drug sellers to register their physical location with the DEA and maintain all relevant state licenses required for the operation of their website.[123] A bona fide physician-patient relationship must also theoretically exist in order for prescriptions to be filled.[124] The DEA addresses the illegality and possible criminal consequence for consumers who purchase and import controlled substances from foreign Internet sites. It also regulates attempts to provide consumer information on how to identify illegal sites, the reporting of illegal drug sales, and the risks inherent to Internet drug sellers.[125] The DEA has followed up its initial 2001 guidance with additional consumer alerts aimed at reinforcing the illegality and possible criminal consequences for purchasing controlled substances, such as narcotic pain relievers, sedatives, stimulants and anabolic steroids, without a valid prescription.[126] As the agency directly responsible for narcotic drugs of abuse, the DEA emphasizes that illegal Internet drug sellers represent not only a public health risk, but also the evolution of traditional illicit drug dealers to the distribution and sale of drugs via cyberspace.[127]

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[118] *Pharmaceutical Sales Over the Internet: Hearing Before the H. Comm. on Government Reform*, 108th Cong. (2003) (statement of William Hubbard, Associate Commissioner for Policy, Planning, and Legislation, U.S. Food and Drug Administration), *available at* http://www.fda.gov/ola/2003/pharmsales0327.html.

[119] *See* Frank, *supra* note 96.

[120] *See* Dispensing and Purchasing Controlled Substances over the Internet, 66 Fed. Reg. 21181 (Apr. 27, 2001), *available at* http://www.deadiversion.usdoj.gov/fed_regs/notices/2001/fr0427.htm.

[121] *See id.*

[122] *See id.*

[123] *See id.*

[124] *See id.*

[125] *See id.*

[126] *See* Press Release, U.S. Drug Enforcement Administration, DEA Warning-Buying Drugs Online May Be Illegal and Dangerous!, http://www.deadiversion.usdoj.gov/consumer_alert.htm.

[127] *See id.*

In April 2005, the DEA, FDA, and CBP[128] announced the results of the year-long Operation Cyber Chase, which the DEA had implemented with the help of several foreign governments, to crack down on illegal online drug sellers distributing controlled substances without a prescription.[129] As a result of this operation, twenty individuals in eight U.S. cities and four foreign countries, who were members of an Internet drug trafficking organization that used 200 websites to sell millions of pills globally, forfeited over $6 million of illicit proceeds.[130]

Although Operation Cyber Chase has been touted as a significant step against illegal online distribution of drugs and a successful collaboration between U.S. and international law enforcement agencies, analysis of the operation's results rebut this conclusion. The difficulty of locating and prosecuting criminals in international jurisdictions, a failure to address systemic problems such as the high cost of pharmaceuticals, and questions regarding the cost-benefit of attempting to locate undetectable and advanced criminals using traditional law enforcement techniques, all raise the important issue of whether enforcement alone can truly make an impact on the potential dangers of international Internet drug sellers.[131]

In fact, despite the notable efforts of Operation Cyber Chase, other operations such as Operation CyberX,[132] as well as recent additional efforts,[133]

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[128] In addition, the Federal Bureau of Investigation ("FBI"), U.S. Postal Service, and Internal Revenue Service participated in the operation.

[129] *See* John R. Castronova, *Operation Cyber Chase and Other Agency Efforts to Control Internet Drug Trafficking: The "Virtual" Enforcement Initiative Is Virtually Useless*, 27 J. LEGAL MED. 207, 207-208 (2006).

[130] *See* Karen Tandy, Administrator, U.S. Drug Enforcement Administration, Address at Operation Cyber Chase Press Conference (Apr. 20, 2005), http://www.usdoj.gov/dea/speeches/s042005.html.

[131] *See* Castronova, *supra* note 129, at 221-22; *see also* Testimony of John Theriault, *supra* note 52, at 8-9 (indicating the global nature of online drug sales, including a "doctor" issuing a prescription in one location, a pharmacy at another, the origin of the drug at another, the website at another, and the computers serving the portal and anchor sites at two more).

[132] The DEA reports that since October 2005 it has initiated over 236 investigations into online pharmacies, seized over $14.5 million dollars in assets in FY2004 as a result of these actions, stemmed the flow of pharmaceutical supply to illegal online drug sites through the success of inter-agency cooperation in investigations such as "Operation CYBERx" which involved the Office of National Drug Policy (ONDCP), Immigration and Customs Enforcement (ICE), Customs and Border Patrol (CBP) and the FDA. *See The National Synthetic Drug Control Strategy: Hearing on the Synthetic Drug Control Strategy Before the Subcomm. on Criminal Justice, Drug Policy and Human Resources of the H. Comm. on Govt. Reform*, 109th Cong. (2006) (statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA), *available at* http://www.usdoj.gov/dea/pubs/cngrtest /ct061606.html. More recently, the DEA reported that for 2007, it seized assets valued at $39.4 million. *See* Federica Narancio, *DEA Seeks New Restrictions on Internet Pharmacies*, MCCLATCHY, June 25, 2008, *available at* http://www.mcclatchydc.com/251/story/42082.html.

Note also that other governmental groups work on this area, but have limited jurisdiction. For example, the Federal Trade Commission ("FTC") also works to address online drug sales. The FTC's role in addressing the practices of online pharmacies is derived from the agency's authority as promulgated in Section 5 of the Federal Trade Commission Act, which allows enforcement for the prevention of deceptive or unfair acts or practices in commerce. *See Drugstores on the Net: The Benefits and Risks of Online Pharmacies: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Commerce*, 106th Cong. (2006) (statement of Jodie Bernstein, Director of the Bureau on Consumer Protection, FTC), *available at* http://www.ftc.gov/os/1999/07/pharmacytestimony.htm. Primarily, the FTC

are also having little impact on illegal online drug sales. The proceeds collected from major inter-agency operations do not come close to sales of suspect online drug sellers. For example, one suspect Internet drug seller, MyCanadianPharmacy.com, which has been linked to a major worldwide criminal spamming operation, is estimated to have sales of $150 million annually.[134] Indeed, it is estimated that eighty percent of spam advertises illegal and suspect online drug sales,[135] which completely dwarfs any agency efforts to control these illicit activities.

DEA enforcement efforts are limited by the practicalities of the Internet, particularly offshore where many of the problems arise.[136] A website's anonymous Internet presence and easy removal make it difficult for law enforcement to identify, track, monitor, and shut down foreign-based Internet

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investigates actions in which an Internet pharmacy makes false or misleading claims about the products or services it provides as well as the regulation of marketing practices that cause or are likely to cause substantial consumer injury which is not reasonably avoidable by consumers or outweighed by countervailing benefits to consumers or competition. Actions within the FTC's scope of authority include monitoring websites, conducting investigations, making referrals to other federal and state authorities and also acting through an interagency working group (comprised of the FTC, FDA, DOJ, DEA and other federal and state agencies). *See id.* In addition, the FTC reserves the right to bring action against Internet marketers of health care products for health care fraud on the Internet, such as those actions taken through "Operation Cure All," which may prove to be the most effective tool it can exercise against Internet pharmacies within its limited power. *See id.* However, the FTC specifically notes that it has limited jurisdiction over the Internet pharmacy industry and regulation of these business practices is primarily a function of the state pharmacy boards and the FDA. *See id.*

[133] *See* Narancio, *supra* note 132; *see also* Press Release, U.S. Immigration and Customs Enforcement, Chinese Internet distributor convicted of trafficking in fake prescription drugs (July 7, 2008), http://www.ice.gov/pi/nr/0807/080707houston.htm (describing conviction of Kevin Xu, an Internet drug seller who attempted to sell and distribute fake Plavix, Casodex, Zyprexa, Aricept, and Tamiflu sourced from China).

[134] *See* Menn, *supra* note 19 (describing illegal spamming systems that primarily tout drugs from websites such as MyCanadianPharmacy.com with approximately $150 million in sales annually).

[135] *See id.*; *see also* Wailin Wong, *Feds Bust Alleged Spam Network Behind Billions of Viagra E-mails*, CHI. TRIB., Oct. 14, 2008, *available at* http://www.chicagotribune.com/business/chi-biz-fcc-spam-bust-oct14,0,3147108.story (describing FTC global spam network investigation involving billions of spam notices that involved U.S., New Zealand, Cyprus, and Georgia conspirators using servers in China and worldwide "botnets" - networks of hijacked personal computers to disseminate spam - that made millions of dollars in sales of fake erectile dysfunction drugs made in China and India). Unfortunately, India, and especially China, have been the source of increasing recognition of poor quality drug and other products. *See* Gardiner Harris, *The Safety Gap*, N.Y. TIMES, Oct. 31, 2008, *available at* http://www.nytimes.com/2008/11/02/magazine/02fda-t.html?_r=1&ei=5070&oref=slogin&emc =eta1&pagewanted=all. It should be noted that the ineffectiveness of spam legislation for online drug sales, as well as access to pornography and fraudulent business deals, is additional indicia that current legal efforts are ineffective in addressing Internet sales. *See, e.g.*, Carolyn D. Marsan, *CAN-SPAM: What Went Wrong?*, NETWORK WORLD, Oct. 6, 2008, *available at* http://www.networkworld.com/news/2008/100608-can-spam.html (outlining a ten-fold increase in spam over the last five years despite CAN-SPAM Act of 2003).

[136] These challenges are also faced by state governments, but are exacerbated by the state limitation of jurisdiction within its borders. For example, challenges of state efforts including the inability to assert personal jurisdiction over out-of-state defendants such as international sites, limitations on the regulation of interstate commerce imposed by the commerce clause of the U.S. Constitution as it applies to Internet commerce, difficulties in locating operators of illegal Internet sellers and the extradition of out-of-state defendants. *See* Castronova, *supra* note 129, at 215-17.

drug sellers.[137] Further, globalization has created havens for online sellers such as free trade zones (areas specifically designated by several countries to promote trade by providing low or waived tariffs and reduced regulatory oversight) in order to conceal, manufacture, and market counterfeit drugs.[138] Such a free trade zone was used by RxNorth.com, as discussed above.[139] These free trade zones are often in countries that do not have the expertise, resources, awareness, or desire to detect and deal with the complex issues surrounding online sales of illegal pharmaceuticals.[140]

In situations where identified online sellers are not within U.S. boundaries and thus are not easily subjected to the U.S. law enforcement jurisdictional authority, investigators and agents have little recourse other than to request the applicable foreign government to take action against the website.[141] Since drug laws vary by country, however, enforcement efforts against Internet drug sellers on foreign soil are often thwarted because foreign governments may be reluctant to share information or develop mechanisms to cooperate with U.S. law enforcement efforts.[142] Thus, the Internet creates a virtually impenetrable cloak that allows illegal online sales to go unchecked and unregulated despite extensive efforts to limit this practice and the dangers inherent therein.

V. CURRENT PROPOSALS

Federal efforts to address the problem of online drug sellers have been short-sighted and incomplete. Some of these efforts are described below.

A. Ryan Haight Online Pharmacy Consumer Protection Act of 2008

On October 15, 2008, President Bush signed the Ryan Haight Online Pharmacy Consumer Protection Act of 2008,[143] which amends the Controlled Substances Act to prohibit the delivery, distribution, or dispensing of controlled substances over the Internet without a valid prescription. Named after Ryan Haight, a 17-year-old honor student who tragically lost his life due to an overdose of narcotics purchased from an Internet drug seller, the law regulates online commerce of controlled substances by requiring registration and reporting requirements for online pharmacies.[144] In addition, it requires

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[137] *See* Liang, *supra* note 3 (citing Statement of Richard Stana, *supra* note 112, at 30).

[138] *See* Bogdanich, *supra* note 59.

[139] *See supra* notes 48-60 and accompanying text (describing the RxNorth.com case).

[140] *See* Bogdanich, *supra* note 59.

[141] *See id.*

[142] *See* Liang, *supra* note 3, at 341.

[143] Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, *available at* http://frwebgate.access.gpo.gov/cgibin/getdoc.cgi?dbname=110_cong_bills&docid=f:h6353enr.txt.pdf [hereinafter Ryan Haight Act].

[144] These include: (a) display of adherence to the Act on the online pharmacy's homepage, *see id.* § 311(a); (b) compliance with state licensure requirements, *see id.* § 311(b); (c) disclosure of information regarding contact information of the pharmacy, qualifications of its pharmacist-in-charge and certification of its registration under the Act, *see id.* § 311(d); and (d) notification to the Attorney General and applicable state boards of pharmacy at least 30 days prior to offering to sell, deliver, distribute, or dispense controlled substances over the Internet, *see id.* § 311(e). The bill also provides for (i) enhanced enforcement mechanisms

a valid prescription for drugs, defined as a prescription issued for a legitimate purpose by a practitioner who has conducted at least one in-person medical evaluation of the patient.[145]

Although a commendable effort, the law fails to substantively address key issues associated with online drug sales. First, the primary sources of illegal Internet drug sales are outside the United States. Hence, the challenges of regulating drug sales from internationally-based sellers, the ephemeral nature of Internet presence, and jurisdictional issues noted above[146] are not addressed by the bill's provisions, which focus almost entirely upon domestic activities.[147] In addition, the law is limited in scope to controlled substances and does not include other drugs that can be abused or counterfeited.[148] In attempting to limit harm by requiring a "valid prescription," the law completely ignores the fact that Internet drug pushers often forego such legal niceties through online surveys and brazen sales without verifying any prescriptions at all.[149] Indeed, the bill may even create another illicit source of revenue for these sellers: charging consumers for such "valid prescriptions."[150] The practice of obtaining "valid" prescriptions from online medical consultations is already a growing concern,[151] as consumers increasingly seek to fill these prescriptions, not only online, but also in their local pharmacies.[152]

B. Safeguarding America's Pharmaceuticals Act of 2008

In April 2008, Representative Steve Buyer (R-IN) with eleven co-sponsors introduced H.R. 5839, the Safeguarding America's Pharmaceuticals Act of 2008.[153] This bill would amend the Food, Drug, and Cosmetic Act in an effort to improve the safety of drugs.

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against Internet pharmacies by providing for increased criminal penalties involving controlled substances in Schedules II, IV and V of the Controlled Substances Act, *see id.* § 311(f); and (ii) authorizes states to seek injunctions or obtain damages and other civil remedies against online pharmacies within their jurisdiction, *see id.* § 311(i).

[145] *See id.* § 309(e).

[146] *See supra* notes 128-139 and accompanying text (noting challenges of law enforcement efforts in attempting to regulate offshore Internet drug sales).

[147] *See supra* note 144 (describing provisions).

[148] *See* Ryan Haight Act, *supra* note 143, § 2.

[149] *See* Bryan A. Liang, *Online Pharmacy Bill, A Good Start but Needs More*, The Hill, Sept. 14, 2006, http://thehill.com/op-eds/online-pharmacy-bill-a-good-start-but-needs-more-2006-09-14.html.

[150] This is the same mode of business practice in other illicit pharmaceutical drug sales sites, i.e., over the border in Mexico. Consumers purchase drugs from "farmacias" that have arrangements with "doctors" who will write prescriptions for medications without the need for a medical exam for as low as $20. *See* Mary P. Flaherty & Gilbert M. Gaul, *Millions of Americans Look Outside U.S. for Drugs*, Wash. Post, Oct. 23, 2003, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/06/28/AR2007062801634_5.html.

[151] *See* Nat'l Ctr. on Addiction and Substance Abuse at Columbia University, *supra* note 6, at 4 ("Some rogue Internet pharmacies provide online consultations free of charge; others refer customers to 'script doctors' who are willing to write prescriptions for a fee . . . ranging from $10 to $180.").

[152] *See id.* at 14.

[153] Safeguarding America's Pharmaceuticals Act of 2008, H.R. 5839, 110th Cong. (2008), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?bname=110_cong_bills&docid=f:h5839ih.txt.pdf.

The bill would mandate that the federal government develop a drug identification and tracking system to prevent counterfeits from entering the supply chain.[154] It specifically requires drug pedigrees and directs the Secretary of Health and Human Services to submit a feasibility report for using radio-frequency identification ("RFID"), bar code, and other identification technologies.[155] In particular, the bill, would establish new distributor licensing standards,[156] as well as require unique serial numbers for all prescription drugs,[157] pedigrees starting with the wholesale distributor,[158] and track-and-trace systems.[159] It would also provide funding for small pharmacies to help such pharmacies implement the necessary technology.[160]

Most importantly, the bill attempts to address the concerns associated with Internet drug sellers by authorizing the FDA to seize and destroy drugs at U.S. ports of entry.[161] As noted by Rep. Buyer, suspect drugs from Internet sources predominate in the U.S. mail system:

> Of the thousands of [I]nternet pharmacies selling drugs to Americans today, only 15 are licensed by the National Association of Boards of Pharmacy [VIPPS Accreditation Program]. Many of these non-licensed [I]nternet pharmacies purchase the drugs they sell from areas of the world where counterfeit drug manufacturers are prolific, such as China and India, and the safety of these drugs is largely unknown . . . .
>
> In one day, up to 360,000 packages containing counterfeit drugs enter our 12 international mail facilities—that is up to 10 million packages a month and 130 million counterfeit drug packages in a year. The Food and Drug Administration (FDA) screens less than one percent of these packages before they are sent through our domestic mail system. The less than one percent of the packages that are screened and found to contain counterfeit drugs are returned to the sender by the FDA. Time and time again, FDA screeners see packages make a one to two week turn around for re-entry into the mail facilities, after initially being rejected and returned to the sender, making way to unassuming Americans.[162]

Although this key provision of the bill—which empowers the FDA to destroy contraband and counterfeit drugs—is an important step forward, the primary weakness was identified by the sponsor of the bill himself. With less than one percent of drugs entering the U.S. mails screened due to the limited

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154 *See id.* §§ 5-6.

155 *See id.* §5. Note that there are significant weaknesses in the use of technology such as RFID to address problems in the legitimate supply chain. *See* Liang, *supra* note 3 *passim*; Liang, *Structurally Sophisticated or Lamentably Limited?*, *supra* note 39 *passim* (discussing limitations of technology in its current state for drug supply safety).

156 *See* Safeguarding America's Pharmaceuticals Act, *supra* note 153, §10.

157 *See id.* § 5.

158 *See id.* § 6.

159 *See id.* § 5.

160 *See id.* § 7.

161 *See id.* § 13.

162 *See* Buyer, *supra* note 110.

human resources[163] as well as the policy issues relating to identification and release of these packages,[164] the overwhelming number of drugs coming from suspect Internet drug sellers by U.S. mail are simply too numerous for the FDA to stem the tide, even given their power to destroy these materials in the highly unlikely event they are detected.

C. Safe Internet Pharmacy Act of 2007

In February 2007, Senator Judd Gregg (R-NH) and two co-sponsors introduced S. 596, the Safe Internet Pharmacy Act of 2007,[165] which would amend the Food, Drug and Cosmetic Act to regulate Internet drug sellers.

The bill would require the Secretary of Health and Human Services to license Internet pharmacies, requiring state licensure for any state in which the Internet pharmacy sells and dispenses drugs.[166] This requirement would include both online drug sellers within and outside the U.S.[167] The bill would also render void any effort of the Internet drug seller to limit liability through hold harmless agreements.[168] Finally, the bill would require any online drug seller to list its physical address and the states in which it has a license to dispense drugs. The online drug seller would also have to affirm that it will only dispense drugs after receipt of a valid prescription from a treating provider.[169]

The Secretary would maintain a database of licensed Internet pharmacies.[170] License application fees would provide funding,[171] and the Secretary may award a contract to operate the licensing program.[172]

The bill exempts "providers of interactive computer services or advertising services" such as search engines from liability for prohibited Internet drug sales if they do not own or operate the Internet drug site.[173] It directs the Federal Reserve Board to promulgate regulations that establish policies and procedures to prevent illegal online drug sale financial transactions,[174] and exempts financial institutions that follow these policies and procedures from liability for refusing to execute transactions.[175]

This bill is notable because it confronts Internet drug sellers directly. Provisions authorizing licensure by the Secretary and limiting hold harmless

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[163] *See* U.S. Department of Health and Human Services, *supra* note 109, at 56 (noting only 16.9 FTE of the FDA assigned to all international mail facilities).

[164] *See supra* note 112 and accompanying text (noting that suspect packages not inspected by FDA within 24 hours released to U.S. Postal Service for delivery).

[165] Safe Internet Pharmacy Act of 2007, S. 596, 110th Cong. (2007), *available at* http://thomas.loc.gov/cgi-bin/query/z?c110:S.596.

[166] *See id.* § 511(c).

[167] *See id.*

[168] *See id.* § 511(c)(2)(A)(iv). Note that this may apply to hold harmless agreements that states with Canadian importation programs require to be signed before patient access. *See supra* text accompanying note 39 (discussing state importation programs and access only after signing waivers).

[169] *See id.* § 511(c)(2)(B).

[170] *See id.* § 511(c)(4).

[171] *See id.* § 511(c)(5).

[172] *See id.* § 511(c)(9).

[173] *See id.* § 511(d).

[174] *See id.* § 511(e).

[175] *See id.* § 511(e)(3)(A).

agreements are commendable. The proposed system for informing the public of appropriately licensed Internet pharmacies would allow consumers to determine the specific pharmacies that are legitimate Internet sellers. In addition, creating a federal regulatory system of financial oversight to identify and stem illegal online sales of drugs is also an important step forward in addressing the lack of regulation and accountability in online drug sales.

One great weakness in this bill, however, is its exemption from accountability of Internet search engines. As noted previously, search engines in particular obtain proceeds and profits from online purveyors of drugs, legal and illegal.[176] Their facilitation of the activities of online drug sellers and their profits gained therefrom make them part and parcel of the problem. Because these profits are ill-gained at the expense of patient safety, public health, and social welfare, the search engines must be held accountable for the at best tacit and at worst conspiratorial approval and facilitation of these clearly illegal sales.

VI. A PROPOSED STATUTE

A. Overview

It is apparent that online drug sales, or perhaps more appropriately stated, Internet drug pushing, is a common and limited risk endeavor—at least for the pusher. The volume and scope of websites touting drugs and U.S. mail containing illicit materials simply overwhelm the limited regulatory power of both law enforcement and FDA personnel. Further, the easily avoided "quality" requirements and the ability of search engines to profit off of unscrupulous, illegal, and unsafe sales creates poor incentives to ensure safety of online drug sales. As well, the ready market of vulnerable patient populations creates a steady source of illicit demand. Finally, the effortless consummation of illegal drug sales through credit card and other financial transactions allows online sellers and Internet search engines to easily profit from this activity. Each of these issues must be addressed in order to thwart the danger of illicit online drug sales.

B. An Annotated Bill

To accomplish these goals, a statutory means is the most direct and efficient.[177] Accordingly, this paper proposes a bill on the federal level.[178]. The following sections include the text of the proposed bill and a detailed analysis of each provision.

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[176] *See supra* notes 40-41 and accompanying text.

[177] *See, e.g.*, Richard A. Epstein, *The Social Consequences of Common Law Rules*, 95 Harv. L. Rev. 1717 (1982) (noting that legislation is a more efficient and effective method to achieve social change than common law).

[178] An unannotated version of the bill is included in the Appendix.

- **General Provisions and Definitions**

A Bill

H.R. ——

To amend the Food, Drug, and Cosmetic Act to provide for access to safe, authentic drugs via the Internet, and for other purposes.

A BILL

To amend the Food, Drug, and Cosmetic Act to provide for access to safe, authentic drugs via the Internet, and for other purposes.

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Safe Online Drug Purchasing Act."

SECTION 2. TO ENSURE ACCOUNTABILITY AND ACCESS TO SAFE, AUTHENTIC DRUGS VIA THE INTERNET.

(a) Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq) is amended by inserting after section 511 the following:

"SEC. 511-1. ACCOUNTABILITY AND ACCESS TO SAFE, AUTHENTIC DRUGS VIA THE INTERNET.

"(a) FINDINGS.—Congress makes the following findings:

"(1) Medicines provide significant benefits to citizens of this country.

"(2) However, due to lack of knowledge and affordability issues, many citizens, particularly vulnerable patients such as minorities, seniors, and those lacking insurance, may attempt to access medicines from suspect sources, such as the Internet.

"(3) The Internet is a high risk source of medications, and many Internet sellers are engaged in illegal sales as well as the provision of low quality and counterfeit products.

"(4) Patients are harmed and/or killed by illicit online drug sales.

"(5) Lack of clear regulatory rules allows illicit online drug sales to proliferate despite law enforcement efforts.

"(6) Profit-oriented online search engines and limited accountability measures have failed to ensure legitimate and safe drug sales over the Internet.

"(7) The ease by which financial transactions can be executed and limited focus on policies to block illegal online drug sales promotes illicit pharmaceutical sales over the Internet.

"(b) DEFINITIONS.—In this section:

"(1) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

"(2) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

"(3) DEPARTMENT.—The term 'Department' shall mean the Department of Health and Human Services unless otherwise specified.

"(4) DESIGNATED PAYMENT SYSTEM.—The term 'designated payment system' means any system utilized by a financial transaction provider that the Secretary of the Treasury and Board, in consultation with the Attorney General, jointly determine, by regulation or order, could be utilized in connection with, or to facilitate, any restricted transaction.

"(5) ELECTRONIC FUND TRANSFER.—The term 'electronic fund transfer"—

"(A) has the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

"(B) includes any fund transfer covered under article 4A of the Uniform Commercial Code, as in effect in any State.

"(6) FINANCIAL INSTITUTION.—The term 'financial institution'—

"(A) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

"(B) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

"(7) FINANCIAL TRANSACTION PROVIDER.—The term 'financial transaction provider' means a creditor, credit card issuer, financial institution, operator of a terminal at which an electronic fund transfer may be initiated, money transmitting business, or international, national, regional, or local payment network utilized to effect a credit transaction, electronic fund transfer, stored value product transaction, or money transmitting service, or a participant in such network, or other participant in a designated payment system.

"(8) INTERNET.— The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor successor protocols to such protocol, to communicate information of all kinds by wire or radio.

"(9) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person or entity that offers to dispense or dispenses in the United States a prescription drug through an Internet website in interstate commerce, regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

"(10) INTERNET SEARCH ENGINE.—The term 'Internet search engine' or 'search engine' means a service made available via the Internet that, on the basis of query consisting of terms, concepts, questions, or other data input by a user, searches information available on the Internet and returns to the user a means, such as a hyperlinked list of Uniform Resource Identifiers, of locating, viewing, or downloading information or data available on the Internet relating to that query.

"(11) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meanings given the terms in section 5330(d) of title 31, United States Code.

"(12) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

"(13) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of a individual who places an unlawful Internet pharmacy request to any person engaged in the operation of an unlicensed Internet pharmacy, of—

"(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful Internet request (including credit extended through the use of a credit card);

"(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful Internet request;

"(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful Internet request and is drawn on or payable at or through any financial institution; or

"(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful Internet request.

"(14) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services, unless otherwise specified.

"(15) STATE.—The term 'State' means any State of the United States, the District of Columbia, or any commonwealth, territory, or other possession of the United States.

"(16) TREATING PROVIDER.—The term 'treating provider' means a health care provider licensed in the United States who is authorized to prescribe medications and who—

"(A)(i) performs a documented patient evaluation (including an in-person patient history and physical examination) of an individual, portions of which may be conducted by other health professionals;

"(ii) discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and

"(iii) maintains contemporaneous medical records concerning the individual; or

> "(B) provides care to an individual as part of an on-call or cross-coverage arrangement with a health care provider described in subparagraph (A).
>
> "(17) UNLICENSED INTERNET PHARMACY.—The term 'unlicensed Internet pharmacy' means an Internet pharmacy that is not licensed under this section.
>
> "(18) UNLAWFUL INTERNET PHARMACY REQUEST.—The term 'unlawful Internet pharmacy request' means the request, or transmittal of a request, made to an unlicensed Internet pharmacy for a prescription drug by mail (including a private carrier), facsimile, telephone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.
>
> "(19) WEBPAGE.—The term 'webpage' means a location, with respect to the World Wide Web, that has a—
>
> "(A) single Uniform Resource Locator; or
>
> "(B) single location with respect to the Internet, as such location may be prescribed by the Federal Trade Commission.
>
> "(20) WEBSITE.—The term 'website' means a collection of webpages that are presented and made available by means of the World Wide Web as a single website or webpage with a—
>
> "(A) common domain name; or
>
> "(B) common ownership, management, or registration."

The bill's preamble and Sections 1 and 2 describe the reason and the purpose of the Act, and note that it will amend the FDCA.[179] Section 2 of the bill introduces a new proposed FDCA Section 511-1. In subsection (a), the key aspects of the problem of online drug sales are noted: vulnerable patient populations, limited regulation, the potential for poor quality and counterfeit product, deaths and injuries from online drug purchases, lack of search engine accountability, and ease of financial transactions. Definitions for the forthcoming substantive sections are given in subsection (b) to provide clarity in understanding the scope of the new provisions.

- **511-1(c)(1) – National Low Cost/No Cost Drug Access Program**

As previously indicated, vulnerable patients who are particularly price-sensitive are more likely to purchase drugs from suspect online sources.[180] Hence, the first priority should be to provide these populations with access to legitimate drugs to break the chain of illicit demand. The next provision of the bill establishes a federal low cost/no cost drug program that can address this problem by using a defined standardized set of criteria for determining populations most vulnerable to dangerous illicit online drug sales.[181]

> "(c) ACCESS TO SAFE DRUGS.—
>
> "(1) NATIONAL LOW COST/NO COST DRUG ACCESS PROGRAM.—The Secretary shall direct the Department of Health and Human Services Office of Minority Health to—
>
> "(A) identify private and public low and no-cost prescription drug programs in the United States of America, including those with health literacy, culturally competent, and language translation services, and identify all state-level Offices of Minority Health;
>
> (B) develop an integrated, national program, the National Low Cost/No Cost Drug Access Program ("DAP"), to provide access to low and no-

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[179] 21 U.S.C. §§501-511 (2006).

[180] *See* NATIONAL CONSUMERS LEAGUE, *supra* note 23 (discussing price-sensitive vulnerable patient populations who purchase drugs online).

[181] *See* Liang, *supra* note 3, at 369-84 (proposing an access program to address issues of price and authenticity).

> cost drugs for minority and vulnerable patient populations under 400% of the federal poverty levels, utilizing and expanding upon programs identified in subsection (c)(1)(A) above, with the assistance of the Department Advisory Committee on Minority Health, state-level Offices of Minority Health, and industry members and groups, as appropriate;
>
> "(C) work with State governments to integrate the DAP developed in (c)(1)(B) to also enroll participants into eligible health programs, such as, but not limited to, Medicaid, State Children's Health Insurance Programs, Supplemental Security Income, Medicare Part D, state high risk insurance programs, and other programs;
>
> "(D) provide outreach and access to DAP for minority and vulnerable patient populations; and
>
> "(E) develop appropriate education, terms, and conditions of participation to ensure that access to drugs is provided to minority, Medicare Part D enrolled, and vulnerable patient populations, and that identification of any adverse reactions or events associated with these drugs are noted, reported, and disseminated."

DAP has several substantive policy advantages. It would weaken—if not break—the chain between suspect online drug sellers and vulnerable patient populations. With access to drugs from legitimate sellers in a government-sponsored program, these patients who otherwise must choose risky sources could obtain authentic, legitimate drugs.

In addition, DAP could build upon previous programs and proposals. The pharmaceutical industry's trade group, the Pharmaceutical Research and Manufacturers of America, has an initiative known as the Partnership for Prescription Assistance ("PPA").[182] PPA is a clearinghouse of information and enrollment for public and private programs that provide no cost/low cost drugs to those in need.[183] This program could serve as a basis for DAP. PPA has important characteristics which ensure that vulnerable patient groups have access to legitimate drugs. It is culturally sensitive, with prescription assistance available in multiple languages, and it provides for phone assistance, which is important for literacy challenged adults.[184] In addition, were DAP adopted as a federal regulation, the Department of Health and Human Services Office of Minority Health[185] and its state equivalents' programmatic knowledge of health care systems and populations would assist in the creation and implementation of the DAP.[186] Hence, DAP development would not need to be created from scratch, but could instead be built upon existing efforts and an established knowledge base that could make implementation less costly.

Further, an integrated DAP program could serve as a basis for enrollment in and outreach for public insurance programs. In this way, DAP could

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[182] *See* Partnership for Prescription Assistance, http://www.pparx.org (last visited Feb. 5, 2009).

[183] *See id.*

[184] The phone number for the Partnership for Prescription Assistance is 1-800-4PPA-NOW (1-800-477-2669). *See id.*; *see also* Bryan A. Liang, *Addressing Limited English Proficiency: A Call for Action to Promote Patient Safety*, 3 J. PATIENT SAFETY 57 (2007) (discussing limited literacy and English proficiency as important issues for consideration in promoting safe drug access).

[185] *See* Home Page – The Office of Minority Health, http://www.omhrc.gov (last visited Feb. 5, 2009).

[186] *See* Advisory Committee on Minority Health – The Office of Minority Health, www.omhrc.gov/templates/content.aspx?ID=3872 (last visited Feb. 5, 2009).

promote access to health care by connecting those eligible for public programs services in a culturally competent, and socially appropriate manner.[187] This approach could supplement current outreach methods and thus increase access not only to medicines but also to health care coverage.[188]

Importantly, the DAP provisions also allow for opportunities to monitor adverse drug reactions in vulnerable patient populations. This is a key concern because minority patients and seniors rarely participate in clinical trials for drugs. Hence, primary and side effects on these patient populations are not well known.[189] Provisions in DAP for collecting and reporting adverse drug reactions would enhance research opportunities with respect to these underrepresented groups.

- **511-1(c)(2) – Participation in the Drug Access Program**

Drug company participation in DAP is essential for providing the broad spectrum of medicines required for the program. This can be accomplished by linking FDA review of drugs for marketing approval with DAP program participation:

> "(2) PARTICIPATION IN NATIONAL LOW COST/NO COST DRUG ACCESS PROGRAM.—
>
> "(A) FDA DRUG REVIEW.—Any drug that has received, or that receives, marketing approval after August 1, 1997 under section 505(b)(1) of this Act, section 505(b)(2) of this Act, section 505(j) of this Act, or under section 351 of the Public Health Service Act, shall be required to participate in the DAP developed under paragraph (c)(1)(B) of this section.
>
> "(B) TERMS OF PARTICIPATION.—
>
> "(i) TIME.—Drugs subject to this paragraph must be available for distribution in the DAP within 18 months of the date of drug marketing application approval by the FDA, or within 18 months of the establishment of the DAP for those drugs already approved for marketing by the FDA at the time the DAP begins.
>
> "(ii) DURATION.—Drugs subject to this paragraph approved under section 505(b)(1) or section 505(b)(2) of the Food, Drug, and Cosmetic Act, and under section 351 of the Public Health Service Act must participate in the DAP for 15 years after the date of marketing approval, or until the drug is withdrawn from the market; drugs subject to this paragraph approved under section 505(j) of the Food, Drug, and Cosmetic Act must participate in the DAP for 10

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[187] Unfortunately, many patients are eligible for public health insurance but do not access it. *See, e.g.*, Gregory D. Stevens et al., *Enrolling Vulnerable, Uninsured But Eligible Children in Public Health Insurance: Association with Health Status and Primary Care Access*, 117 PEDIATRICS e751 (2006) (noting greater than two-thirds of uninsured children in California are eligible for public health insurance coverage). A program that links drug access with health insurance would have great potential to increase the percentage of insureds.

[188] *See, e.g.*, SARA R. COLLINS ET AL., A ROADMAP TO HEALTH INSURANCE FOR ALL: PRINCIPLES FOR REFORM (2007), http://www.commonwealthfund.org/usr_doc/Collins_roadmaphltinsforall_1066.pdf?section=4039 (finding that access to health insurance is directly related to access to high quality care).

[189] *See, e.g.*, Dorie Hightower, *Minority Participation in Clinical Trials*, BENCHMARKS, Sept. 6, 2006, http://www.cancer.gov/newscenter/benchmarks-vol6-issue4 (noting that minorities are particularly underrepresented in cancer clinical trials); GOVERNMENT ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: FDA GUIDANCE AND REGULATIONS RELATED TO DATA ON ELDERLY PERSONS IN CLINICAL DRUG TRIALS (2007) (noting effects of drugs not known on seniors because many clinical trials exclude them from participation and calling for better FDA oversight).

> years after the date of marketing approval, or until the drug is withdrawn from the market. Drugs approved after August 1, 1997 and before the date the DAP begins shall be deemed to have participated in the DAP as of the date of FDA marketing approval."

DAP participation would hence be required for FDA review of brand name and generic drugs seeking marketing approval as well as already approved drugs. From a social welfare perspective, this arrangement is a valid expression of the social contract, allowing pharmaceutical companies access to the lucrative U.S. drug market in exchange for FDA review and participation in DAP.[190]

The bill also includes in DAP older, approved drugs, if approved after August 1, 1997, to allow participants access to medicines already on the market. This specific date is chosen because it was the date the FDA issued the draft guidance for direct-to-consumer drug advertising that has accounted for increased pharmaceutical company profits.[191]

To ease transition into the regulatory system proposed by this bill, this proposal provides for a grace period of eighteen months. This period allows drug companies to begin distribution and sales before DAP participation for

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[190] Brand name drug companies do fund a fraction of the costs associated with new chemical or biologic drug application review. *See, e.g.*, Prescription Drug User Fee Rates for Fiscal Year 2007, 71 Fed. Reg. 43,780 (July 26, 2006); Prescription Drug User Fee Amendments of 2002, 21 U.S.C. §379g (2006); *see also* SUSAN THAUL, CONGRESSIONAL RESEARCH SERVICE, THE PRESCRIPTION DRUG USER FEE ACT (PDUFA): BACKGROUND AND ISSUES FOR PDUDA IV REAUTHORIZATION 14 (2007), *available at* http://opencrs.cdt.org/rpts/RL33914_20070313.pdf (reporting that in Fiscal Year 2006, user fees covered 19.9% of FDA salary and expenses); U.S. FOOD AND DRUG ADMINISTRATION, FY 2005 PDUFA FINANCIAL REPORT 4 (2006), *available at* http://www.fda.gov/oc/pdufa/finreport2005/PDUFA05finrpt.pdf (reporting user fees accounted for 56% of all FDA funds from all sources in support of human drug application review). At the present time, generic drug applications are not funded by generic company applicants. But citizens through their government fund the balance. In addition, clinical trials require participation by citizens, and research funded by public grant funded work and research performed by the National Institutes of Health, the National Science Foundation, and others, benefit pharmaceutical companies. Hence, an exchange between pharmaceutical companies and the public that allows for monopoly pricing via the patent regime, resources for additional innovation, and a focus on legitimate drugs being used by patients in exchange for FDA review, participation in the DAP building on extant industry programs, and increased access by vulnerable patient populations is a reasonable exchange. Indeed, this exchange can be considered a bargain for pharmaceutical companies because the marginal costs associated with making the next dose of a particular drug is extremely small. *See, e.g.*, Asymptomatically Free Goods, http://arnoldkling.com/~arnoldsk/aimst5/aimst506.html (Feb. 24, 2002) (noting "The marginal cost of manufacturing prescription drugs is low."); Patricia M. Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT'L J. HEALTH CARE FIN. & ECON. 183, 185 (2003) ("Marginal cost [of drug production and sales] includes only the variable cost of producing and selling additional units, which is usually very low.").

[191] *See The Impact of Direct-to-Consumer Drug Advertising on Seniors Health Care and Health Costs: Hearing before the Special Comm. on Aging*, 109th Cong. (2005) (statement of Rachel E. Behrman Deputy Director, Office of Medical Policy, U.S. Food and Drug Administration), *available at* http://www.fda.gov/ola/2005/idcda0929.html; M.B.Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 NEW ENG. J. MED. 498 (2002); M.B.Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 NEW ENG. J. MED. 498 (2002); T.V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149 (1999); KAISER FAMILY FOUNDATION, IMPACT OF DIRECT-TO-CONSUMER ADVERTISING ON PRESCRIPTION DRUG SPENDING (2003), http://www.kff.org/rxdrugs/6084-index.cfm.

new drugs. However, due to drug patent monopolies, newly approved drugs must participate in DAP for at least fifteen years, whereas generic and other abbreviated application forms with a more limited life would only be required to participate in DAP for ten years.[192]

The bill accounts for the amount of time older drugs, in both brand name and generic forms, have been on the market by deeming DAP participation to have started as of the date of FDA marketing approval. This limits the duration of these drugs' inclusion in DAP.

It should be noted that because of the public-based nature of DAP, the patients benefiting from this program would be segregated from the private system. It would therefore be economically rational for drug companies to participate in DAP because of the limited spill-over into private markets coupled with the traditionally low cost of marginal production of drugs that could be made available for DAP beneficiaries.[193]

- **511-1(c)(3) – Prohibition of Internet Sales**

As previously discussed, regulating Internet drug sales implicates tremendous safety issues that must be addressed. A bright line prohibition of online drug sales would send a clear statutory message to would-be Internet drug sellers and buyers:

> "(3) PROHIBITION OF DRUG SALES VIA IMPORTATION AND THE INTERNET.—
> "(A) All drugs approved by the FDA that receive marketing approval under section 505(b)(1) of this Act, section 505(b)(2) of this Act, section 505(j) of this Act, or under section 351 of the Public Health Service Act—
> "(i) shall not be permitted to be imported, except under

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[192] Drug approvals by the FDA are under the Food, Drug, and Cosmetic Act and the Public Health Service Act. New drug applications, or NDAs, are evaluated under section 505(b)(1) and (b)(2) of the Food, Drug, and Cosmetic Act. 21 U.S.C. §355(b)(1)-(2) (2000). Every new chemical drug, such as the familiar prescription pills obtained from a pharmacy is reviewed under the NDA premarketing process by the FDA and must be approved by the FDA before sale, as described in §505(b)(1). *See* Bryan A. Liang, *Regulating Follow-On Biologics*, 44 HARV. J. ON LEGIS. 363, 367, 384-86 (2007). Generic chemical drugs are reviewed using an abbreviated approach under the Abbreviated New Drug Application (ANDA), section 505(j) of the Food, Drug, and Cosmetic Act, 21 U.S.C. §355(j) (2000). *See id.* at 386-90. Biologic medicines, such as vaccines, cancer drugs, and other injectable drugs, which are much larger and complex compared with chemical medicines, *see id.* at 368-69, are regulated as both drugs under section 505(b)(2) of the Food, Drug, and Cosmetic Act and as biologics under section 351 of the Public Health Service Act, 42 U.S.C. §262 (2004). With respect to smaller biologics, such as insulin and growth hormone, they are usually reviewed under a parallel NDA application process delineated by section 505(b)(2) of the Food, Drug, and Cosmetic Act, whereas new, larger, and more complex biologics are regulated under the Biological License Application process, or BLA, under section 351 of the Public Health Service Act, which is similar in scope to the NDA process. *See id.* at 390-92.

[193] As Danzon & Towse note:

> [E]ven though patents may in theory enable a firm to charge a price above marginal cost, this may not be in the firm's self-interest in markets where consumers cannot afford to pay. Thus, a patent-holder may rationally set prices near marginal cost in low-income markets where demand is highly price-elastic, provided that these low prices cannot spill-over to other, potentially higher-priced markets in the same country or other countries.

Danzon & Towse, *supra* note 190, at 185-86; *see also supra* note 190 and accompanying text (discussing bargain for pharmaceutical companies in social contract because of limited cost of producing marginal unit of drugs).

> the provisions of the section 381(d)(1) of this Act; and
>
> "(ii) shall not be subject to sale through an unlicensed Internet pharmacy.
>
> "(B) Only Internet pharmacies licensed by the Secretary in accordance with this section shall be permitted to sell prescription drugs through the Internet."

These general provisions establish the foundational rule that no Internet drug sales are permitted. This prohibition includes importation through state-based programs. Only Internet pharmacies that are in fact licensed under this section are permitted to sell drugs online. This statement thus provides private and public stakeholders with notice as to the legality of online drug sales, and the message that the federal government is taking a prime and active role in regulating this area.[194]

- **511-1(c)(4) – Government Authority to Destroy Contraband Drugs**

As noted previously,[195] federal officials have limited power to destroy contraband drugs detected through the mail system. Legal reform to effectively allow FDA, CBP, DEA and other federal agencies to promote consumer safety must address this policy failure:

> "(4) DESTRUCTION OF ADULTERATED, MISBRANDED, COUNTERFEIT, AND PRESCRIPTION DRUGS IN VIOLATION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—
>
> "(A) Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—
>
> "(i) in the third sentence—
>
> "(I) by striking 'or (3) such' and inserting '(3) such'; and
>
> "(II) by inserting ', or (4) such article is a counterfeit drug,' before 'then such article shall be refused admission'; and
>
> "(ii) by striking 'Clause (2) of the third sentence of this paragraph' and inserting 'Notwithstanding the preceding sentence, the Secretary of the Treasury shall cause the destruction of any such article refused admission if (1) the article is a drug, the article appears to be adulterated, misbranded, or in violation of section 505 or 511-1, and the article has a value less than $2,000 or such amount as the Secretary of Health and Human Services may determine by regulation; or (2) the article appears to be a counterfeit drug. Clause (2) of the third sentence of this subsection'.

This provision amends the FDCA to allow for destruction of adulterated, misbranded, counterfeit drugs, as well as those that do not comport with the FDCA. This gives the relevant law enforcement agencies power to ensure that

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[194] This may be important in preemption considerations. *See, e.g.*, Bryan A. Liang, *Patient Injury Incentives in Law*, 17 YALE L. & POL'Y REV. 1, 23 (1998) (discussing federal preemption when Congress may so completely preempt a particular area that any complaint raising a select group of claims is necessarily federal in character and removable to federal court, even if a federal issue does not appear on the face of the plaintiff's complaint).

[195] *See supra* notes 108-10 and accompanying text (discussing legal challenges to destroy contraband materials intercepted in the mails).

this contraband is easily accessed and destroyed if and when it is detected.[196] Because only licensed Internet pharmacies would be permitted to sell drugs, the total number of suspect packages would be reduced and identification of contraband enhanced. Law enforcement efforts would thus have an appreciable effect on blocking illegal sales by illicit sellers.

- **511-1(c)(5) – Pharmacy Verification System**

Use of VIPPS or other equivalent accountability structures and federal licensure would create a manageable and distinct set of sellers from whom buyers could legitimately and safely purchase drugs over the Internet. This infrastructure would serve as a foundation for the creation of a standard and reliable set of legitimate online pharmacies:

> "(5) LICENSING OF INTERNET PHARMACIES.—
>
> "(A) IN GENERAL.—An Internet pharmacy shall be licensed by the Secretary in accordance with this section prior to offering to sell or dispense a prescription drug to any individual.
>
> "(B) BASIC PROVISIONS FOR INTERNET PHARMACY LICENSING.—The Secretary shall ensure that the licensing program in this section comports with all the requirements of the National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Site accreditation program.
>
> "(C) CONDITIONS FOR LICENSURE.—Notwithstanding subparagraph (B) of this section, the Secretary shall also ensure that licensing of Internet pharmacies includes:
>
> "(i) verification of that all employees and agents of the Internet pharmacy are in compliance with applicable Federal and State laws with respect to the practice of pharmacy, including licensing laws and inspection requirements, and manufacturing and distribution of controlled substances, including with respect to mailing or shipping controlled substances to consumers;
>
> "(ii) verification that the Internet pharmacy expressly and affirmatively agrees to provide and maintain an agent for service of process in the United States and be subject to the jurisdiction of the United States and any of its States or territories where it engages commerce;
>
> "(iii) verification that the Internet pharmacy agrees to affix to each shipping container of drugs to be shipped in and to the United States such markings as the Secretary determines to be necessary to identify that shipment is from a licensed Internet pharmacy, which may include anti-counterfeiting and track-and-trace technologies;
>
> "(iv) verification that the Internet pharmacy shall permit inspection of the facilities and business practices of the Internet pharmacy by the Secretary at any time to determine it is in compliance with this section;
>
> "(v) verification that no agreement exists that releases the Internet pharmacy, and any employee or agent of the Internet pharmacy, from liability for damages arising out of the negligence or willful act of the Internet pharmacy or negligent execution of or willful act regarding an unlawful Internet pharmacy request, and any such limitation of liability shall be null and void;
>
> "(vi) verification that the Internet pharmacy shall dispense prescription drugs to purchasers only after a receipt of a valid

[196] This paper adopts for the most part the provisions from section 3 of Representative Buyers' bill to accomplish this goal. *See* Safeguarding America's Pharmaceutical Act, *supra* note 153.

> prescription from a treating provider who is licensed to practice in the State in which the consumer resides;
>
> "(vii) verification that the Internet pharmacy shall post in a clear and visible manner on each page of the website of the Internet pharmacy:
>
> "(I) the street address, city, zip or other comparable mail code, State or other comparable entity, country, and telephone number of—
>
> "(aa) each place of business of the Internet pharmacy;
>
> "(bb) the name(s) of each supervising pharmacist of the Internet pharmacy and each State license number under which he or she dispenses drugs, and each individual who serves as a pharmacist for purposes of the Internet pharmacy website and each State license number under which he or she dispenses drugs."

These provisions begin the substantive process of regulation of online drug sellers. It should be emphasized that the Secretary must use the NABP VIPPS program, rather than such limited and ineffective "verified" programs such as PharmacyChecker.com in creating the licensing program for online drug sellers. In contrast to PharmacyChecker.com, VIPPS mandates drug sellers to fulfill a wide array of quality and safety requirements, including supporting documentation, an on-site survey, and agreement to program policies.[197] VIPPS also requires state licensure information, pharmacist-in-charge licensure, internal pharmacy policies, website information, adherence to patient privacy rights, authentication activities, security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.[198] Further, under VIPPS, accreditation is not static; re-surveys of pharmacies can occur anytime in the event of a complaint.[199] In this way, VIPPS avoids the lax oversight characteristic of PharmacyChecker.com, which allows online drug sellers to violate its "requirements" while maintaining "verified" status.

However, this proposed bill mandates other, more specific requirements beyond the VIPPS accreditation requirements.[200] These include legally-oriented provisions such as compliance with controlled substances laws, agreement to have a domestic agent and U.S. jurisdiction over legal matters, and elimination of limited liability or hold harmless clauses. The proposed bill also includes safety and accountability issues such as surprise inspections

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[197] *See* National Association of Boards of Pharmacy – Verified Internet Pharmacy Practice Sites (VIPPS), *supra* note 43. Note, however, that this describes the full VIPPS accreditation program, and does not refer to the more recently established "mid-level" group status that appear to comply with pharmacy practice law but remain unaccredited. *See, e.g.*, National Association of Boards of Pharmacy, *NABP Creates Middle Tier for Unaccredited Internet Pharmacies That Appear to Comply with Pharmacy Law, Practice Standards*, June 27, 2008, REUTERS, *available at* http://www.reuters.com/article/pressRelease/idUS194999+27-Jun-2008+PRN20080627.

[198] *See* National Association of Boards of Pharmacy – Verified Internet Pharmacy Practice Sites (VIPPS), *supra* note 43.

[199] *See id.*

[200] This paper includes some definitions and modifies some of the provisions from Senator Gregg's Safe Internet Pharmacy Act of 2007 in its proposed FDCA section 511(a)(4) and section 511(c)(2). *See* Safe Internet Pharamacy Act of 1007, *supra* note 165.

of the Internet pharmacy, identification of Internet pharmacy products on all shipped packages, encouraged use of anti-counterfeiting technology, and a listing of the Internet pharmacy's physical location.

The bill addresses the cyber-doctor problem directly by requiring that Internet drug sellers dispense drugs only after receiving a valid prescription from a "treating provider" licensed in the patient's state. Recall that under the bill's definitions, a "treating provider" must perform an in-person history and physical examination of the patient. This provision is consonant with the American Medical Association's position on the issue, which requires a substantive physician-patient relationship that ensures appropriate clinical basis for the prescription and potential for follow up.[201] The bill hence mandates a substantive provider-patient relationship with a provider licensed in the state of the patient before a valid prescription can issue and be filled by the Internet pharmacy.

- **511-1(d) – Additional Conditions for Internet Pharmacy Licensure**

As noted previously, vulnerable patient populations are not often included in clinical trials. It is therefore of great importance to collect information on adverse events in relation to these populations.[202] In addition to the previously discussed proposed bill provisions regarding the collection of data,[203] licensed Internet pharmacies should thus be mandated to keep records of patients (under appropriate privacy standards), to establish a procedure for patients to report adverse events and submit these reports to the FDA quickly, and to create effective communications systems to inform their patients of medication recalls and warnings as a condition of licensure to sell online:

> "(d) ADDITIONAL CONDITIONS FOR LICENSURE.—In addition to subparagraph (c)(5)(B) and (C) of this section, Internet pharmacies shall:
>
> "(1) Maintain patient medication records and other relevant information to allow appropriate consultation to ensure clinical prospective drug use review and notice

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[201] The AMA takes a strong position on Internet prescribing by physicians and has issued policy document H-120.949 to emphasize that physicians who prescribe over the Internet shall establish or have established a valid patient-physician relationship based on AMA criteria for an acceptable clinical encounter and follow up. *See* AMERICAN MEDICAL ASSOCIATION, GUIDANCE FOR PHYSICIANS ON INTERNET PRESCRIBING 97, *available at* http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.pdf. This guidance on Internet prescribing also limits prescribing across state lines and specifically mentions that physicians who prescribe only using online questionnaires or online consultation may be subject to greater personal liability exposure and have not met the appropriate medical standard of care. *See id.*; *see also* AMERICAN MEDICAL ASSOCIATION, DIRECTIVES OF THE AMA HOUSE OF DELEGATES 34, http://www.ama-assn.org/ad-com/polfind/Directives.pdf. The AMA expresses its desire to develop model federal legislation addressing Internet pharmacies which includes the following elements: (a) mandatory accreditation by the VIPPS program; (b) in order to be valid, prescriptions must be authorized by a U.S. licensed physician with a valid patient-physician relationship; (c) mandatory disclosure of identifying information; and (d) authorizing the federal government to take action against ISPs and credit card processors against non certified sites. *See supra* note 34 and accompanying text (noting "cyber doctors" are violating standards of the Federation of State Medical Boards, DEA, as well as the American Medical Association).

[202] *See supra* note 189 and accompanying text (describing limited participation of minorities and seniors in clinical trials).

[203] *See supra* § (c)(1)(E) of the proposed bill.

> regarding medication warnings, adverse events, and other information;
>
> "(2) Ensure that records are confidential and protected in accordance with regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;
>
> "(3) Establish a mechanism in accordance with requirements of the Secretary that allows patients to report errors and suspected adverse drug events, which shall include:
>
> "(A) documentation of the response of the Internet pharmacy to the patient report; and
>
> "(B) documentation that the patient report has been forwarded on to the FDA in accordance with the requirements of the Secretary within 72 hours of receipt;
>
> "(4) Establish a patient notification system in accordance with requirements of the Secretary of medication recalls and warnings to patients who have ordered such medications from the Internet pharmacy."

This subsection requires, as a condition of Internet pharmacy licensure, the collection of appropriate clinical information and patient data that otherwise may not be reported or documented. It also mandates a system of error and adverse event reporting—an extremely important consideration for detecting unknown clinical issues with medications that have not been previously determined for vulnerable patient populations. The bill further requires communication of important circumstances regarding drug warnings and recalls using systems that can electronically transmit information to patients who have ordered the drug. Note that patient records must adhere to the Health Insurance Portability and Accountability Act of 1996, the federal medical information privacy rule,[204] to ensure appropriate patient confidentiality protection.

- **511-1(e) – Licensing Procedures**

Once a set of requirements for licensure is established, details as to a procedure for application, renewal, suspension, and termination as well as listing and information dissemination of these approved Internet pharmacies is required. These provisions can be accomplished as noted below.

> "(e) LICENSING PROCEDURE AND DATABASE.—
>
> "(1) ELECTRONIC FILING.—The Secretary shall create a licensing application system for Internet pharmacies that shall use electronic methods to submit information for the Secretary to review the Internet pharmacy's compliance with the requirements under this Act.
>
> "(2) AUTHENTICATION.—The Secretary shall ensure that adequate authentication protocols are used to validate and verify all information in the Internet pharmacy licensing application.
>
> "(3) DATABASE AND TOLL FREE NUMBER.—The Secretary shall compile, maintain, and periodically update a database of Internet pharmacies licensed under this section and make such information available to the public on an Internet webpage on the Department's website and through a toll-free telephone number.
>
> "(4) LICENSING APPLICATION FEE.—The Secretary shall create a licensing application fee to be paid by all Internet pharmacy applicants, and such fee shall be determined annually by the Secretary based on the anticipated costs to the Secretary for administration and enforcement of the requirements of this section in the subsequent fiscal year.
>
> "(5) SUSPENSION.—
>
> "(A) IN GENERAL.—The Secretary may immediately suspend the

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[204] *See* 45 C.F.R. §§ 160-64 (2006).

> license of an Internet pharmacy if he or she finds that such Internet pharmacy is engaged in a violation of any requirement of this Act.
>
> "(B) APPEAL.—Any Internet pharmacy may appeal the suspension order if such appeal occurs within 30 days of the suspension in subsection (5)(A).
>
> "(C) APPEAL PROCEDURE.—The Secretary shall, given the requirement of subsection (B), provide an opportunity for an informal hearing to affirm or terminate the suspension order within 30 days of the appeal. If, however, the Secretary does not provide such an opportunity for a hearing or to affirm or terminate the order, the suspension order shall be deemed terminated.
>
> "(D) NO JUDICIAL REVIEW.—Any suspension order by the Secretary shall not be subject to judicial review.
>
> "(6) LICENSE TERMINATION.—The Secretary shall terminate an Internet pharmacy license issued under this Act after notice to the Internet pharmacy and an opportunity for a hearing if the Secretary has determined that the Internet pharmacy—
>
> "(A) has made an untrue statement of material fact in its licensing application;
>
> "(B) has shown a pattern of noncompliance with the requirements of this Act; or
>
> "(C) is in violation of any applicable State or Federal law relating to the dispensing of a prescription drug.
>
> "(7) LICENSURE REVIEW.—
>
> "(A) IN GENERAL.—Any Internet pharmacy license issued under this Act shall be reviewed annually to determine if the Internet pharmacy is in compliance with the terms of this Act.
>
> "(B) RENEWAL.— Renewal of an Internet pharmacy's license under this Act—
>
> "(i) shall not occur if any of the provisions in subsection (6) are found by the Secretary.
>
> "(ii) must include testing of the Internet pharmacy website, the methods by which the Internet pharmacy communicates with patients, and a physical inspection of records and premises of the Internet pharmacy.
>
> "(8) CONTRACTING FOR PROGRAM ADMINISTRATION AND OPERATION.—
>
> "(A) ADMINISTRATION.—The Secretary may award a contract under this subsection for Internet pharmacy program administration and operation.
>
> "(B) OTHER RESPONSIBILITIES.—In addition to the provisions under subparagraphs (e)(1)-(7), the recipient of a contract to administer and operate the Internet pharmacy licensing program shall also—
>
> "(i) identify unlicensed Internet pharmacy websites or Internet pharmacy websites that are acting in violation of Federal or State laws with respect to dispensing drugs;
>
> "(ii) report such Internet pharmacy websites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General, the Secretary, and any other appropriate authority for further investigation; and
>
> "(iii) submit each fiscal year for which the contracting award under this subsection is made, a report to the Secretary describing investigations under subsection (i) and the outcomes thereof."

This section outlines the administrative requirements with respect to Internet pharmacies. It mandates electronic filing for licensing, which can reduce costs and improve efficiency. The Secretary must establish validation and verification systems to ensure that Internet pharmacy license applicants provide accurate and appropriate information in their applications. This is an important step to avoid the clear lack of accountability seen in current verification systems such as PharmacyChecker.com. Further, the bill provides for public access to the names of licensed pharmacies, including publication

on the Department's website and a toll-free number. Application fees, as determined by the Secretary on the basis of anticipated costs, would support the fiscal underwriting of the program.

In addition, the bill provides the Secretary with the ability to rapidly suspend an Internet pharmacy's licensure and thereby protect patients from ongoing violations. There is also a provision for appeal of this suspension. The Department may terminate the Internet seller's license should it determine that the seller has engaged in a verified pattern of noncompliance with the license requirements, lied on an application for licensure, or violated federal prescription drug dispensing laws.

The bill requires that the Secretary take into account previous noncompliant actions to determine re-licensure of the Internet pharmacy, as well as specific testing and verification of the Internet pharmacy's records and locale. This latter verification ensures that an Internet pharmacy does not engage in illegal drug-selling behavior after obtaining its initial licensure. Finally, the Secretary has the power to award a contract to administer the program.[205] An express provision for the contractee to actively seek out and report suspect Internet drug sellers ensures continued vigilance against illegal online sales.

- **511-1(f) – Search Engine Accountability**

A critical aspect of any effort to reign in the abuses and harm associated with unfettered Internet drug sales is to assign accountability to Internet search engines which have, up until now, given short shrift to safety of products that they advertise and the illegal transactions from which they profit. The following section of the proposed bill adopts a strategy of focusing upon financial transaction proceeds to thereby disincentivize such sales. Further, search engines must address consumers' lack of knowledge or naïveté concerning Internet drug sales, since search engines are in the best position to provide this information to patients at the point of search.

"(f) PROHIBITION OF ACCEPTANCE OF ANY FINANCIAL INSTRUMENT FOR AN UNLAWFUL INTERNET PHARMACY REQUEST.—

"(1) IN GENERAL.—No person may knowingly accept in connection with the participation of another person in an unlawful Internet pharmacy request—

"(A) credit, or the proceeds of credit, extended to or on behalf of such other person (including credit extended through the use of a credit card);

"(B) an electronic fund transfer, or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of such other person;

"(C) any check, draft, or similar instrument which is drawn by or on behalf of such other person and is drawn on or payable at or through any financial institution; or

"(D) the proceeds of any other form of financial transaction, as the Secretary of the Treasury and the Board may jointly prescribe by regulation, which involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of such other person.

"(2) INTERNET SEARCH ENGINE INCLUSION.—

"(A) The prohibitions in subsection (f) of this section are expressly applicable to search engines if they accept any proceeds in the forms indicated

[205] Perhaps a good contractee for this role would be the National Association of Boards of Pharmacy.

> in subsection (f)(1) as obtained for any advertisement of any Internet pharmacy if such search engines knew or should have known that the Internet pharmacy was an unlicensed Internet pharmacy under the terms of this Act or otherwise knew or should have known that the Internet pharmacy was engaged in restricted transactions or fulfilling or attempting to fulfill an unlawful Internet pharmacy request.
>
> "(3) INTERNET SEARCH ENGINE BANNER ON INTERNET DRUG SALES.—All search engines shall have a banner displayed prominently above any drug and other medication search results that—
>
> "(A) states that Internet drug sales are illegal unless performed by a Department of Health and Human Services licensed Internet pharmacy; and
>
> "(B) includes a link to the Department of Health and Human Services webpage that lists licensed Internet pharmacies."

This subsection prohibits any person from accepting the proceeds of an illegal drug sale that occurs over the Internet.[206] Hence, it prevents illegal online drug sellers from receiving the proceeds of their activities through electronic means, and significantly reduces their ability to profit from these sales. Further, to address the tacit approval and limited oversight of search engines of this illegal activity, the bill expressly prohibits search engines from receiving proceeds from advertisements of unlicensed Internet pharmacies or those websites that solicit unlawful Internet pharmacy requests. Thus, in contrast to other legislative proposals that would immunize Internet search engines,[207] this bill would hold in violation search engines that profit from ignoring illegal online drug sales if they knew or should have known of such activities.

Additionally, to address the uninformed consumer as well as to direct him or her to appropriate licensed Internet pharmacies, this bill mandates search engines to display a banner referencing the law regarding online drug sales and directing the patient to the Department of Health and Human Services website of licensed Internet pharmacies. The banner must be shown on the screen above any drug name search results. This provision in combination with financial transaction regulation will help limit the number of illegal sales and promote the exclusive use of legitimate Internet pharmacies.

- **511-1(g) – Prevention of Illicit Transactions**

Also complicating the issue of illicit Internet drug sales is the fact that financial transactions over the Internet are complex. As a preventive matter, the challenges of identifying and intercepting unlawful Internet pharmacy requests should be studied to limit harm from unregulated online drug sales.

> "(g) POLICIES AND PROCEDURES TO IDENTIFY AND PREVENT RESTRICTED TRANSACTIONS.—
>
> "(1) REGULATIONS.—Within 180 days after enactment of this section, the Secretary of the Treasury and the Board in consultation with the Attorney General shall prescribe regulations requiring each designated payment system, and all participants therein, to identify and block or otherwise prevent or prohibit restricted transactions through the establishment of policies and procedures reasonably designed to identify and block or otherwise prevent or prohibit the introduction of restricted transactions into a

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[206] Such an approach is similar to the ban of accepting funds for illegal Internet gambling. *See* 31 U.S.C. §5363 (2007) (banning the acceptance of funds from bettors by online gambling websites).

[207] *See* Safe Internet Pharmacy Act of 2007, *supra* note 165, § 511(d).

> designated payment system or the completion of restricted transactions using a designated payment system.
>
> "(2) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under paragraph (1), the Board shall—
>
> "(A) identify types of policies and procedures, including nonexclusive examples, that shall be considered reasonably designed to prevent the introduction of a restricted transaction in a designated payment system or the completion of restricted transactions using a designated payment system; and
>
> "(B) to the extent practical, permit any participant in a payment system to choose among alternative means of preventing the introduction or completion of restricted transactions.
>
> "(3) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—
>
> "(A) IN GENERAL.—A person that identifies and blocks a transaction, prevents or prohibits the acceptance of its products or services in connection with a transaction, or otherwise prevents the completion or refuses to honor a transaction shall not be liable to any party for such action if—
>
> "(i) the transaction is a restricted transaction;
>
> "(ii) such person reasonably believes the transaction to be a restricted transaction; or
>
> "(iii) as a designated payment system or a member of a designated payment system or financial transaction provider in reliance on the policies and procedures of the payment system, such person takes the action in an effort to comply with regulations prescribed under subsection (g)(1).
>
> "(B) NO LIABILITY FOR REFUSING TO HONOR NONRESTRICTED TRANSACTION.—A person who prevents or otherwise refuses to honor a nonrestricted transaction in a good faith effort to implement the policies and procedures under this subsection or to otherwise comply with this section shall not be liable to any party for such action.
>
> "(4) ENFORCEMENT.—This subsection shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided by section 505(a) of the Gramm-Leach-Bliley Act (21 U.S.C. 6805(a))."

In this part of the bill, the provisions mandate the study and creation of regulations to preventively block unlawful Internet pharmacy requests. Harmonizing the provisions of the Unlawful Internet Gambling Enforcement Act[208] and the proposed Safe Internet Pharmacy Act of 2007,[209] this bill establishes a regulatory means of intercepting and blocking restricted Internet transactions. At the same time, the bill provides that compliance with such regulations precludes liability for blocking nonrestricted transactions if done in good faith. This system thus allows persons reporting suspect restricted transactions and designated service payments systems to err on the side of caution without worrying about incurring liability.

These provisions would be enforced by the Federal Reserve as well as the Federal Trade Commission ("FTC"). FTC oversight is particularly important because the FTC regulates all entities that are not subject to Federal Reserve or other financial regulation under the broad authority of the Federal Trade Commission Act.[210]

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208 31 U.S.C. § 5364 (2006).

209 Safe Internet Pharmacy Act of 2007, *supra* note 165, § 511(e).

210 15 U.S.C. §§ 41-58 (2006).

- **511-1(h) – Civil Remedies**

Finally, it is important that the provisions of these rules be enforced by appropriate penalties. The scourge of illegal Internet drug sales is a serious and severe burden on society and should be treated as such. Both civil and criminal penalties are necessary to support law enforcement efforts:

> "(h) CIVIL REMEDIES.—
>
> "(1) JURISDICTION.—In addition to any other remedy under current law, the district courts of the United States shall have original and exclusive jurisdiction to prevent and restrain restricted transactions by issuing appropriate orders in accordance with this Act, regardless of whether a prosecution has been initiated.
>
> "(2) PROCEEDINGS.—
>
> "(A) INSTITUTION BY FEDERAL GOVERNMENT.—
>
> "(i) IN GENERAL.—The United States, acting through the Attorney General, may institute proceedings under this section to prevent or restrain a restricted transaction.
>
> "(ii) RELIEF.—Upon application by the United States under this section, the district court may enter a temporary restraining order, a preliminary injunction, or an injunction against any person to prevent a restricted transaction.
>
> "(B) INSTITUTION BY STATE ATTORNEY GENERAL.—
>
> "(i) IN GENERAL.—The attorney general (or other appropriate state official) of a State in which a restricted transaction allegedly has been or will be initiated, received, or otherwise made may institute proceedings under this section to prevent or restrain the violation or threatened violation.
>
> "(ii) RELIEF.—Upon application by the attorney general (or other appropriate State official) of an affected State under this section, the district court may enter a temporary restraining order, a preliminary injunction, or an injunction against any person to prevent a restricted transaction."

These proposed provisions allow quick action against websites attempting to fulfill unlawful Internet pharmacy requests. Both federal and state authorities may obtain civil injunctions to prevent restricted transactions, thus allowing for early legal enforcement on the state or federal level to prevent harm associated with inappropriate online drug sales.[211]

- **511-1(i) - Criminal Penalties**

The provisions that may have the greatest impact in deterring these illegal and harmful online drug sales are criminal penalties. Because of the tremendous harm associated with such activities, this bill proposes broad-based criminal liability of unregulated online drug sales participants.

> "(i) CRIMINAL OFFENSES.—
>
> "(1) IN GENERAL.—Except as authorized by this section, it shall be unlawful for any person to knowingly or intentionally—
>
> "(A) deliver, distribute, or dispense any prescription drug by means of the Internet;
>
> "(B) advertise the distribution of, or to offer to sell, distribute, or dispense, a prescription drug by means of the Internet; or
>
> "(C) aid or abet (as such terms are used in section 2 of title 18, United States Code) any activity described in subparagraph (A) or (B) that is not

[211] *See* 31 U.S.C. § 5365 (2006) (allowing for civil remedies to prevent unlawful Internet gambling transactions).

> authorized by this section.
> "(2) EXAMPLES.—Examples of activities that violate paragraph (1) include, but are not limited to, knowingly or intentionally—
> "(A) delivering, distributing, or dispensing a prescription drug by means of the Internet by an unlicensed Internet pharmacy;
> "(B) writing a prescription for a prescription drug for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of this Act;
> "(C) serving as an agent, intermediary, or other entity that causes the Internet to be used to bring together a buyer and seller to engage in dispensing of a prescription drug in a manner not authorized by this Act;
> "(D) offering to fill a prescription for a prescription drug based solely on a consumer's completion of an online medical questionnaire; or
> "(E) making a materially false, fictitious, or fraudulent statement or representation in an Internet pharmacy license application under paragraph (c)(5) of this section.
> "(3) CRIMINAL PENALTIES.—
> "(A) IN GENERAL.— Section 303(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(a)) is amended by adding at the end the following:
> "(3) Any person who violates section 511-1(i) shall be fined under title 18, imprisoned for not more than 10 years, or both.
> "(4) Notwithstanding paragraph (1), (2), or (3), any person who engages in any conduct in violation of this Act that is the proximate cause of the death of the consumer, the term of imprisonment shall be any term of years or for life."

In this section, the bill describes the actors that may be involved in illegal online sales and the criminal penalties they may incur. The bill attaches criminal penalties not only to the act of sale, distribution, or dispensing illicit drugs, but also to any Internet offer or advertisement thereof. Further, the bill attaches aiding and abetting liability to each illegal act ensuring that all responsible agents are reachable.[212]

Importantly, as the nonexclusive examples in subsection (2) indicate, criminal prohibitions are intended to cover the spectrum of those persons and actions that could be involved in illegal online drug sales: an unlicensed Internet pharmacy; a physician who prescribes inappropriately; an agent that facilitates the illegal transaction, including search engines; actions involving online surveys as a basis for a prescription; and lying to obtain an Internet pharmacy license.

The penalties specified in the bill attempt to match the crime. For instance, the bill specifies that illegal activities resulting in the death of a patient may be penalized by life imprisonment. This ensures that those who would push drugs illegally over the Internet realize the seriousness with which legal authorities pursue these crimes.

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[212] 18 U.S.C. § 2 (2006) provides:
(a) Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission, is punishable as a principal.
(b) Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal.

VII. CONCLUSION

Unfettered access to drugs online is a tremendous patient safety issue. Current incentives and penalties are ineffective and limited in addressing the harms associated with illicit online drug sales. Certainly, if anesthesia equipment, sutures, scalpels, and other operating room paraphernalia were easily accessible through Internet search engines and sold and used by unlicensed sellers and consumers on themselves and their families, policymakers would quickly act. Yet medicines, which have an equal—and perhaps greater—potential to harm, have not generated such attention.

Making Internet drug sales illegal unless websites are licensed as legitimate Internet pharmacies addresses many of the issues surrounding these illicit activities. Contraband materials would be more easily identified and destroyed. This would reduce the burden on law enforcement agents and FDA personnel because of the limited and identifiable number of legitimate sellers permitted to sell drugs via the Internet and U.S. mail.

Further, such a system would also put Internet search engines on notice that illicit online sales are strictly prohibited. The current tacit or even express profiteering off of illegal drug sales would therefore be actionable, both civilly and criminally.

A system of federal licensure that generates an easily accessible list of approved Internet drug sellers and advertisers would make investigation of legitimacy simple. Search engines could easily determine if a potential drug advertiser is licensed to sell drugs over the Internet. The system would thus expose search engines that are not performing under the law.

Holding providers accountable for unprofessional activities and practice is also an important component to addressing illicit online sales. It is simply unacceptable for any healthcare provider to discount or dismiss patient safety and medical ethics to facilitate online drug pushing and profits. Severe sanctions in the accountability system reflect both the harm they pose as well as the violation of public trust represented by their participation in online drug pushing.

By making any receipt of financial proceeds from these requests illegal as well as blocking financial transactions involving illicit drug profits, the entire rationale for this illegal activity—monetary gain—is significantly limited for both search engines as well as illicit drug sellers.

Finally, and perhaps most importantly, creating a no-cost/low-cost Drug Access Program may minimize or eliminate the patient demand for these high risk sources. By ensuring that those who cannot afford drugs have access to them, vulnerable patient populations would be able to obtain authentic drugs from trusted sources and have less incentive to turn to questionable Internet drug sources.

Each time a patient purchases a drug online, the benefits of the transaction accrue only to the illicit seller and the search engine facilitator. The patient bears all the risk—the risk of untreated disease, the risk of physical harm, and the risk of death. Online drug pushers enable a world of unregulated abuse drugs that may harm or kill, and the sale of counterfeits of life-saving drugs that cannot cure. We cannot let the lessons of such tragic deaths as Ryan Haight's go unlearned. We must demand that our

policymakers act to ensure that no one must ever bet his or her life on the legitimacy of an online drug seller.

Appendix

A Bill

H.R. ——

To amend the Food, Drug, and Cosmetic Act to provide for access to safe, authentic drugs via the Internet, and for other purposes.

A BILL

To amend the Food, Drug, and Cosmetic Act to provide for access to safe, authentic drugs via the Internet, and for other purposes.

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Safe Online Drug Purchasing Act."

SECTION 2. TO ENSURE ACCOUNTABILITY AND ACCESS TO SAFE, AUTHENTIC DRUGS VIA THE INTERNET.

(a) Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq) is amended by inserting after section 511 the following:

"SEC. 512. ACCOUNTABILITY AND ACCESS TO SAFE, AUTHENTIC DRUGS VIA THE INTERNET.

"(a) FINDINGS.—Congress makes the following findings:

"(1) Medicines provide significant benefits to citizens of this country.

"(2) However, due to lack of knowledge and affordability issues, many citizens, particularly vulnerable patients such as minorities, seniors, and those lacking insurance, may attempt to access medicines from suspect sources, such as the Internet.

"(3) The Internet is a high risk source of medications, and many Internet sellers are engaged in illegal sales as well as the provision of low quality and counterfeit products.

"(4) Patients are harmed and/or killed by illicit online drug sales.

"(5) Lack of clear regulatory rules allows illicit online drug sales to proliferate despite law enforcement efforts.

"(6) Profit-oriented online search engines and limited accountability measures have failed to ensure legitimate and safe drug sales over the Internet.

"(7) The ease by which financial transactions can be executed and limited focus on policies to block illegal online drug sales promotes illicit pharmaceutical sales over the Internet.

"(b) DEFINITIONS.—In this section:

"(1) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

"(2) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

"(3) DEPARTMENT.—The term 'Department' shall mean the Department of Health and Human Services unless otherwise specified.

"(4) DESIGNATED PAYMENT SYSTEM.—The term 'designated payment system' means any system utilized by a financial transaction provider that the Secretary of the Treasury and Board, in consultation with the Attorney General, jointly determine, by regulation or order, could be utilized in connection with, or to facilitate, any restricted transaction.

"(5) ELECTRONIC FUND TRANSFER.—The term 'electronic fund transfer"—

"(A) has the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

"(B) includes any fund transfer covered under article 4A of the Uniform Commercial Code, as in effect in any State.

"(6) FINANCIAL INSTITUTION.—The term 'financial institution'—

"(A) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

"(B) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

"(7) FINANCIAL TRANSACTION PROVIDER.—The term 'financial transaction provider' means a creditor, credit card issuer, financial institution, operator of a terminal

at which an electronic fund transfer may be initiated, money transmitting business, or international, national, regional, or local payment network utilized to effect a credit transaction, electronic fund transfer, stored value product transaction, or money transmitting service, or a participant in such network, or other participant in a designated payment system.

"(8) INTERNET.— The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor successor protocols to such protocol, to communicate information of all kinds by wire or radio.

"(9) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person or entity that offers to dispense or dispenses in the United States a prescription drug through an Internet website in interstate commerce, regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

"(10) INTERNET SEARCH ENGINE.—The term 'Internet search engine' or 'search engine' means a service made available via the Internet that, on the basis of query consisting of terms, concepts, questions, or other data input by a user, searches information available on the Internet and returns to the user a means, such as a hyperlinked list of Uniform Resource Identifiers, of locating, viewing, or downloading information or data available on the Internet relating to that query.

"(11) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meanings given the terms in section 5330(d) of title 31, United States Code.

"(12) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

"(13) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of a individual who places an unlawful Internet pharmacy request to any person engaged in the operation of an unlicensed Internet pharmacy, of—

"(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful Internet request (including credit extended through the use of a credit card);

"(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful Internet request;

"(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful Internet request and is drawn on or payable at or through any financial institution; or

"(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful Internet request.

"(14) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services, unless otherwise specified.

"(15) STATE.—The term 'State' means any State of the United States, the District of Columbia, or any commonwealth, territory, or other possession of the United States.

"(16) TREATING PROVIDER.—The term 'treating provider' means a health care provider licensed in the United States who is authorized to prescribe medications and who—

"(A)(i) performs a documented patient evaluation (including an in-person patient history and physical examination) of an individual, portions of which may be conducted by other health professionals;

"(ii) discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and

"(iii) maintains contemporaneous medical records concerning the individual; or

"(B) provides care to an individual as part of an on-call or cross-coverage arrangement with a health care provider described in subparagraph

(A).

"(17) UNLICENSED INTERNET PHARMACY.—The term 'unlicensed Internet pharmacy' means an Internet pharmacy that is not licensed under this section.

"(18) UNLAWFUL INTERNET PHARMACY REQUEST.—The term 'unlawful Internet pharmacy request' means the request, or transmittal of a request, made to an unlicensed Internet pharmacy for a prescription drug by mail (including a private carrier), facsimile, telephone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

"(19) WEBPAGE.—The term 'webpage' means a location, with respect to the World Wide Web, that has a—

"(A) single Uniform Resource Locator; or

"(B) single location with respect to the Internet, as such location may be prescribed by the Federal Trade Commission.

"(20) WEBSITE.—The term 'website' means a collection of webpages that are presented and made available by means of the World Wide Web as a single website or webpage with a—

"(A) common domain name; or

"(B) common ownership, management, or registration.

"(c) ACCESS TO SAFE DRUGS.—

"(1) NATIONAL LOW COST/NO COST DRUG ACCESS PROGRAM.—The Secretary shall direct the Department of Health and Human Services Office of Minority Health to—

"(A) identify private and public low and no-cost prescription drug programs in the United States of America, including those with health literacy, culturally competent, and language translation services, and identify all state-level Offices of Minority Health;

(B) develop an integrated, national program, the National Low Cost/No Cost Drug Access Program ("DAP"), to provide access to low and no-cost drugs for minority and vulnerable patient populations under 400% of the federal poverty levels, utilizing and expanding upon programs identified in subsection (c)(1)(A) above, with the assistance of the Department Advisory Committee on Minority Health, state-level Offices of Minority Health, and industry members and groups, as appropriate;

"(C) work with State governments to integrate the DAP developed in (c)(1)(B) to also enroll participants into eligible health programs, such as, but not limited to, Medicaid, State Children's Health Insurance Programs, Supplemental Security Income, Medicare Part D, state high risk insurance programs, and other programs;

"(D) provide outreach and access to DAP for minority and vulnerable patient populations; and

"(E) develop appropriate education, terms, and conditions of participation to ensure that access to drugs is provided to minority, Medicare Part D enrolled, and vulnerable patient populations, and that identification of any adverse reactions or events associated with these drugs are noted, reported, and disseminated.

"(2) PARTICIPATION IN NATIONAL LOW COST/NO COST DRUG ACCESS PROGRAM.—

"(A) FDA DRUG REVIEW.—Any drug that has received, or that receives, marketing approval after August 1, 1997 under section 505(b)(1) of this Act, section 505(b)(2) of this Act, section 505(j) of this Act, or under section 351 of the Public Health Service Act, shall be required to participate in the DAP developed under paragraph (c)(1)(B) of this section.

"(B) TERMS OF PARTICIPATION.—

"(i) TIME.—Drugs subject to this paragraph must be available for distribution in the DAP within 18 months of the date of drug marketing application approval by the FDA, or within 18 months of the establishment of the DAP for those drugs already approved for marketing by the FDA at the time the DAP begins.

"(ii) DURATION.—Drugs subject to this paragraph approved under section 505(b)(1) or section 505(b)(2) of the Food, Drug, and Cosmetic Act, and under section 351 of the Public Health Service Act must participate in the DAP for 15 years after the date of

marketing approval, or until the drug is withdrawn from the market; drugs subject to this paragraph approved under section 505(j) of the Food, Drug, and Cosmetic Act must participate in the DAP for 10 years after the date of marketing approval, or until the drug is withdrawn from the market. Drugs approved after August 1, 1997 and before the date the DAP begins shall be deemed to have participated in the DAP as of the date of FDA marketing approval.

"(3) PROHIBITION OF DRUG SALES VIA IMPORTATION AND THE INTERNET.—

"(A) All drugs approved by the FDA that receive marketing approval under section 505(b)(1) of this Act, section 505(b)(2) of this Act, section 505(j) of this Act, or under section 351 of the Public Health Service Act—

"(i) shall not be permitted to be imported, except under the provisions of the section 381(d)(1) of this Act; and

"(ii) shall not be subject to sale through an unlicensed Internet pharmacy.

"(B) Only Internet pharmacies licensed by the Secretary in accordance with this section shall be permitted to sell prescription drugs through the Internet.

"(4) DESTRUCTION OF ADULTERATED, MISBRANDED, COUNTERFEIT, AND PRESCRIPTION DRUGS IN VIOLATION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

"(A) Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—

"(i) in the third sentence—

"(I) by striking 'or (3) such' and inserting '(3) such'; and

"(II) by inserting ', or (4) such article is a counterfeit drug,' before 'then such article shall be refused admission'; and

"(ii) by striking 'Clause (2) of the third sentence of this paragraph' and inserting 'Notwithstanding the preceding sentence, the Secretary of the Treasury shall cause the destruction of any such article refused admission if (1) the article is a drug, the article appears to be adulterated, misbranded, or in violation of section 505 or 512, and the article has a value less than $2,000 or such amount as the Secretary of Health and Human Services may determine by regulation; or (2) the article appears to be a counterfeit drug. Clause (2) of the third sentence of this subsection'.

"(5) LICENSING OF INTERNET PHARMACIES.—

"(A) IN GENERAL.—An Internet pharmacy shall be licensed by the Secretary in accordance with this section prior to offering to sell or dispense a prescription drug to any individual.

"(B) BASIC PROVISIONS FOR INTERNET PHARMACY LICENSING.—The Secretary shall ensure that the licensing program in this section comports with all the requirements of the National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Site accreditation program.

"(C) CONDITIONS FOR LICENSURE.—Notwithstanding subparagraph (B) of this section, the Secretary shall also ensure that licensing of Internet pharmacies includes:

"(i) verification of that all employees and agents of the Internet pharmacy are in compliance with applicable Federal and State laws with respect to the practice of pharmacy, including licensing laws and inspection requirements, and manufacturing and distribution of controlled substances, including with respect to mailing or shipping controlled substances to consumers;

"(ii) verification that the Internet pharmacy expressly and affirmatively agrees to provide and maintain an agent for service of process in the United States and be subject to the jurisdiction of the United States and any of its States or territories where it engages commerce;

"(iii) verification that the Internet pharmacy agrees to affix to each shipping container of drugs to be shipped in and to the

United States such markings as the Secretary determines to be necessary to identify that shipment is from a licensed Internet pharmacy, which may include anti-counterfeiting and track-and-trace technologies;

"(iv) verification that the Internet pharmacy shall permit inspection of the facilities and business practices of the Internet pharmacy by the Secretary at any time to determine it is in compliance with this section;

"(v) verification that no agreement exists that releases the Internet pharmacy, and any employee or agent of the Internet pharmacy, from liability for damages arising out of the negligence or willful act of the Internet pharmacy or negligent execution of or willful act regarding an unlawful Internet pharmacy request, and any such limitation of liability shall be null and void;

"(vi) verification that the Internet pharmacy shall dispense prescription drugs to purchasers only after a receipt of a valid prescription from a treating provider who is licensed to practice in the State in which the consumer resides;

"(vii) verification that the Internet pharmacy shall post in a clear and visible manner on each page of the website of the Internet pharmacy:

"(I) the street address, city, zip or other comparable mail code, State or other comparable entity, country, and telephone number of—

"(aa) each place of business of the Internet pharmacy;

"(bb) the name(s) of each supervising pharmacist of the Internet pharmacy and each State license number under which he or she dispenses drugs, and each individual who serves as a pharmacist for purposes of the Internet pharmacy website and each State license number under which he or she dispenses drugs.

"(d) Additional Conditions for Licensure.—In addition to subparagraph (c)(5)(B) and (C) of this section, Internet pharmacies shall:

"(1) Maintain patient medication records and other relevant information to allow appropriate consultation to ensure clinical prospective drug use review and notice regarding medication warnings, adverse events, and other information;

"(2) Ensure that records are confidential and protected in accordance with regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

"(3) Establish a mechanism in accordance with requirements of the Secretary that allows patients to report errors and suspected adverse drug events, which shall include:

"(A) documentation of the response of the Internet pharmacy to the patient report; and

"(B) documentation that the patient report has been forwarded on to the FDA in accordance with the requirements of the Secretary within 72 hours of receipt;

"(4) Establish a patient notification system in accordance with requirements of the Secretary of medication recalls and warnings to patients who have ordered such medications from the Internet pharmacy.

"(e) Licensing Procedure and Database.—

"(1) Electronic filing.—The Secretary shall create a licensing application system for Internet pharmacies that shall use electronic methods to submit information for the Secretary to review the Internet pharmacy's compliance with the requirements under this Act.

"(2) Authentication.—The Secretary shall ensure that adequate authentication protocols are used to validate and verify all information in the Internet pharmacy licensing application.

"(3) Database and Toll Free Number.—The Secretary shall compile, maintain, and periodically update a database of Internet pharmacies licensed under this

section and make such information available to the public on an Internet webpage on the Department's website and through a toll-free telephone number.

"(4) LICENSING APPLICATION FEE.—The Secretary shall create a licensing application fee to be paid by all Internet pharmacy applicants, and such fee shall be determined annually by the Secretary based on the anticipated costs to the Secretary for administration and enforcement of the requirements of this section in the subsequent fiscal year.

"(5) SUSPENSION.—

"(A) IN GENERAL.—The Secretary may immediately suspend the license of an Internet pharmacy if he or she finds that such Internet pharmacy is engaged in a violation of any requirement of this Act.

"(B) APPEAL.—Any Internet pharmacy may appeal the suspension order if such appeal occurs within 30 days of the suspension in subsection (5)(A).

"(C) APPEAL PROCEDURE.—The Secretary shall, given the requirement of subsection (B), provide an opportunity for an informal hearing to affirm or terminate the suspension order within 30 days of the appeal. If, however, the Secretary does not provide such an opportunity for a hearing or to affirm or terminate the order, the suspension order shall be deemed terminated.

"(D) NO JUDICIAL REVIEW.—Any suspension order by the Secretary shall not be subject to judicial review.

"(6) LICENSE TERMINATION.—The Secretary shall terminate an Internet pharmacy license issued under this Act after notice to the Internet pharmacy and an opportunity for a hearing if the Secretary has determined that the Internet pharmacy—

"(A) has made an untrue statement of material fact in its licensing application;

"(B) has shown a pattern of noncompliance with the requirements of this Act; or

"(C) is in violation of any applicable State or Federal law relating to the dispensing of a prescription drug.

"(7) LICENSURE REVIEW.—

"(A) IN GENERAL.—Any Internet pharmacy license issued under this Act shall be reviewed annually to determine if the Internet pharmacy is in compliance with the terms of this Act.

"(B) RENEWAL.— Renewal of an Internet pharmacy's license under this Act—

"(i) shall not occur if any of the provisions in subsection (6) are found by the Secretary.

"(ii) must include testing of the Internet pharmacy website, the methods by which the Internet pharmacy communicates with patients, and a physical inspection of records and premises of the Internet pharmacy.

"(8) CONTRACTING FOR PROGRAM ADMINISTRATION AND OPERATION.—

"(A) ADMINISTRATION.—The Secretary may award a contract under this subsection for Internet pharmacy program administration and operation.

"(B) OTHER RESPONSIBILITIES.—In addition to the provisions under subparagraphs (e)(1)-(7), the recipient of a contract to administer and operate the Internet pharmacy licensing program shall also—

"(i) identify unlicensed Internet pharmacy websites or Internet pharmacy websites that are acting in violation of Federal or State laws with respect to dispensing drugs;

"(ii) report such Internet pharmacy websites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General, the Secretary, and any other appropriate authority for further investigation; and

"(iii) submit each fiscal year for which the contracting award under this subsection is made, a report to the Secretary describing investigations under subsection (i) and the outcomes thereof.

"(f) PROHIBITION OF ACCEPTANCE OF ANY FINANCIAL INSTRUMENT FOR AN UNLAWFUL INTERNET PHARMACY REQUEST.—

"(1) IN GENERAL.—No person may knowingly accept in connection with the participation of another person in an unlawful Internet pharmacy request—

"(A) credit, or the proceeds of credit, extended to or on behalf of such other person (including credit extended through the use of a credit card);

"(B) an electronic fund transfer, or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of such other person;

"(C) any check, draft, or similar instrument which is drawn by or on behalf of such other person and is drawn on or payable at or through any financial institution; or

"(D) the proceeds of any other form of financial transaction, as the Secretary of the Treasury and the Board may jointly prescribe by regulation, which involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of such other person.

"(2) INTERNET SEARCH ENGINE INCLUSION.—

"(A) The prohibitions in subsection (f) of this section are expressly applicable to search engines if they accept any proceeds in the forms indicated in subsection (f)(1) as obtained for any advertisement of any Internet pharmacy if such search engines knew or should have known that the Internet pharmacy was an unlicensed Internet pharmacy under the terms of this Act or otherwise knew or should have known that the Internet pharmacy was engaged in restricted transactions or fulfilling or attempting to fulfill an unlawful Internet pharmacy request.

"(3) INTERNET SEARCH ENGINE BANNER ON INTERNET DRUG SALES.—All search engines shall have a banner displayed prominently above any drug and other medication search results that—

"(A) states that Internet drug sales are illegal unless performed by a Department of Health and Human Services licensed Internet pharmacy; and

"(B) includes a link to the Department of Health and Human Services webpage that lists licensed Internet pharmacies.

"(g) POLICIES AND PROCEDURES TO IDENTIFY AND PREVENT RESTRICTED TRANSACTIONS.—

"(1) REGULATIONS.—Within 180 days after enactment of this section, the Secretary of the Treasury and the Board in consultation with the Attorney General shall prescribe regulations requiring each designated payment system, and all participants therein, to identify and block or otherwise prevent or prohibit restricted transactions through the establishment of policies and procedures reasonably designed to identify and block or otherwise prevent or prohibit the introduction of restricted transactions into a designated payment system or the completion of restricted transactions using a designated payment system.

"(2) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under paragraph (1), the Board shall—

"(A) identify types of policies and procedures, including nonexclusive examples, that shall be considered reasonably designed to prevent the introduction of a restricted transaction in a designated payment system or the completion of restricted transactions using a designated payment system; and

"(B) to the extent practical, permit any participant in a payment system to choose among alternative means of preventing the introduction or completion of restricted transactions.

"(3) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

"(A) IN GENERAL.—A person that identifies and blocks a transaction, prevents or prohibits the acceptance of its products or services in connection with a transaction, or otherwise prevents the completion or refuses to honor a transaction shall not be liable to any party for such action if—

"(i) the transaction is a restricted transaction;

"(ii) such person reasonably believes the transaction to be a restricted transaction; or

"(iii) as a designated payment system or a member of a designated payment system or financial transaction provider in reliance on the policies and procedures of the payment system, such person takes the action in an effort to comply with regulations

prescribed under subsection (g)(1).

"(B) NO LIABILITY FOR REFUSING TO HONOR NONRESTRICTED TRANSACTION.—A person who prevents or otherwise refuses to honor a nonrestricted transaction in a good faith effort to implement the policies and procedures under this subsection or to otherwise comply with this section shall not be liable to any party for such action.

"(4) ENFORCEMENT.—This subsection shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided by section 505(a) of the Gramm-Leach-Bliley Act (21 U.S.C. 6805(a)).

"(h) CIVIL REMEDIES.—

"(1) JURISDICTION.—In addition to any other remedy under current law, the district courts of the United States shall have original and exclusive jurisdiction to prevent and restrain restricted transactions by issuing appropriate orders in accordance with this Act, regardless of whether a prosecution has been initiated.

"(2) PROCEEDINGS.—

"(A) INSTITUTION BY FEDERAL GOVERNMENT.—

"(i) IN GENERAL.—The United States, acting through the Attorney General, may institute proceedings under this section to prevent or restrain a restricted transaction.

"(ii) RELIEF.—Upon application by the United States under this section, the district court may enter a temporary restraining order, a preliminary injunction, or an injunction against any person to prevent a restricted transaction.

"(B) INSTITUTION BY STATE ATTORNEY GENERAL.—

"(i) IN GENERAL.—The attorney general (or other appropriate state official) of a State in which a restricted transaction allegedly has been or will be initiated, received, or otherwise made may institute proceedings under this section to prevent or restrain the violation or threatened violation.

"(ii) RELIEF.—Upon application by the attorney general (or other appropriate State official) of an affected State under this section, the district court may enter a temporary restraining order, a preliminary injunction, or an injunction against any person to prevent a restricted transaction.

"(i) CRIMINAL OFFENSES.—

"(1) IN GENERAL.—Except as authorized by this section, it shall be unlawful for any person to knowingly or intentionally—

"(A) deliver, distribute, or dispense any prescription drug by means of the Internet;

"(B) advertise the distribution of, or to offer to sell, distribute, or dispense, a prescription drug by means of the Internet; or

"(C) aid or abet (as such terms are used in section 2 of title 18, United States Code) any activity described in subparagraph (A) or (B) that is not authorized by this section.

"(2) EXAMPLES.—Examples of activities that violate paragraph (1) include, but are not limited to, knowingly or intentionally—

"(A) delivering, distributing, or dispensing a prescription drug by means of the Internet by an unlicensed Internet pharmacy;

"(B) writing a prescription for a prescription drug for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of this Act;

"(C) serving as an agent, intermediary, or other entity that causes the Internet to be used to bring together a buyer and seller to engage in dispensing of a prescription drug in a manner not authorized by this Act;

"(D) offering to fill a prescription for a prescription drug based solely on a consumer's completion of an online medical questionnaire; or

"(E) making a materially false, fictitious, or fraudulent statement or representation in an Internet pharmacy license application under paragraph (c)(5) of this section.

"(3) CRIMINAL PENALTIES.—

"(A) IN GENERAL.— Section 303(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(a)) is amended by adding at the end the following:

"(3) Any person who violates section 511-1(i) shall be fined under title 18, imprisoned for not more than 10 years, or both.

"(4) Notwithstanding paragraph (1), (2), or (3), any person who engages in any conduct in violation of this Act that is the proximate cause of the death of the consumer, the term of imprisonment shall be any term of years or for life."