



# The Evolving Regulation of Internet Pharmacies

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# THE EVOLVING REGULATION OF INTERNET PHARMACIES

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Submitted to Professor Peter Barton Hutt as a course paper and in fulfillment of the 3L writing requirement.

## ABSTRACT

This paper follows the rise of the Internet drug sale industry and the response to the trend by regulators, policymakers, and private companies. After discussing the existing laws and their enforcement to police rogue Internet pharmacies, the paper outlines in detail the 2008 Ryan Haight Act and its effect. Finally, the paper analyzes two of the ongoing efforts to tighten the regulation of Internet pharmacies further.

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## 1) INTRODUCTION

As the Internet evolved and pervaded the U.S., parts of the retail market adopted the new technology as an additional medium to reach consumers. When prescription drugs began appearing for sale online, they became particularly popular because they were often cheaper (when sold from outside the U.S.) and easier to obtain (from online pharmacies that wrote prescriptions on the spot, based on a questionnaire). The proliferation of illegal sales of prescription drugs on the Internet has quickly created several challenges for policymakers, enforcement agencies, and consumers. For prosecutors, the shift of the market to a new medium required the use of outdated laws to prosecute a new kind of illegal activity. Policymakers have struggled with striking the right balance between expanding regulatory powers to encompass rogue Internet pharmacies, and leaving existing Internet speech freedoms intact. Finally, rogue Internet pharmacies put the consumers at risk and saturate an online market with illegal activity.

## 2) INTERNET PHARMACIES

### *a. Types of Internet pharmacies*

As other commentators observed, there are three categories of online pharmacies.<sup>1</sup> The main difference between the categories of pharmacies is the requirements they impose on a customer who wishes to purchase a prescription drug. The first category comprises all online pharmacies

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<sup>1</sup> See e.g. Ludmila Bussiki Silva Clifton, Internet Drug Sales: Is It Time to Welcome “Big Brother” into Your Medicine Cabinet?, 20 J. Contemp. Health L. & Pol’y 541, 546 (2004); David L. Baumer, J.C. Poindexter, and Julie Earp, Can Regulation Of Distribution Of Pharmaceutical Products Coexist With Advances In Information Technology, 11 No. 2 J. Internet L. 1, 4 (2007).

that comply with U.S. law, whereas the second and third categories are types of rogue online pharmacies.

First are the legal pharmacies, which verify the existence of a valid prescription by calling the prescribing physician or accepting a copy of the prescription via mail or fax before selling a prescription drug. The websites of all mortar-and-brick pharmacies, such as CVS and Walgreens, fall into the first category of online pharmacies. These pharmacies dispense only FDA-approved drugs, with proper labeling, in proper doses, and only upon a verification of a valid prescription. Legal pharmacies embody what the online market for medical drugs should look like, yet make up a mere 4% of all online pharmacies.<sup>2</sup> The other 96% of Internet pharmacies, which include the pharmacies discussed immediately below, are “rogue.”

The second category of online pharmacies is questionnaire pharmacies. These online pharmacies are often based in the U.S., and work with licensed physicians and pharmacists.<sup>3</sup> Questionnaire pharmacies have gradually formed around a perceived ambiguity of the statutory definition of a physician-patient relationship, and the definition of a valid medical prescription. These pharmacies claim, whether of honest or of convenient belief, that a medical prescription may be issued by the pharmacy’s physician without an in-person consultation, based instead on a health questionnaire or a review of the customer’s medical history. As discussed in part three, this

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<sup>2</sup> National Association of Boards of Pharmacy. Internet Drug Outlet Identification Program, April 2011, <http://www.nabp.net/news/assets/IDOIReportApril11.pdf>.

<sup>3</sup> See The National Center on Addiction and Substance Abuse at Columbia University (CASA), “You’ve Got Drugs! V: Prescription Drug Pushers on the Internet,” July 2008, [www.casacolumbia.org/articlefiles/531-2008%20You've%20Got%20Drugs%20V.pdf](http://www.casacolumbia.org/articlefiles/531-2008%20You've%20Got%20Drugs%20V.pdf); see e.g. <http://www.accessrx.com> (domestic rogue online pharmacy offering prescription drugs based on an online questionnaire).

perceived ambiguity in the law, resolved by federal legislation in 2008, has been perceived unambiguously illegal by nearly all states and the federal agencies all along.<sup>4, 5</sup>

Questionnaire pharmacies based outside the U.S. rely on another perceived legal loophole, based on the misinterpretation of FDA's enforcement policy. On its website, the FDA advises consumers that "it typically does not object to personal imports of drugs that FDA has not approved under certain circumstances," including a situation where (1) the drug is for a serious condition, for which treatment is not available in the U.S., (2) the drug is not sold in the U.S., (3) the drug is considered not to represent an unreasonable risk, (4) the patient verifies in writing that the importation is for personal use only, and (5) the patient does not import more than three-months' worth of drugs.<sup>6</sup> Questionnaire pharmacies often interpret FDA's enforcement policy as an endorsement of all import of drugs for personal use.<sup>7</sup> By maintaining semi-legitimacy, questionnaire pharmacies present a less appealing prosecution target, often staying active for years.

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<sup>4</sup> By 2006, over 40 states considered online questionnaire insufficient for a physician-patient relationship. See Federation of State Medical Boards, Internet Prescribing Language by State, September 2012, <http://www.fsmb.org/pdf/InternetPrescribing-law&policylanguage.pdf>.

<sup>5</sup> See also Drug Enforcement Administration, Dispensing and Purchasing Controlled Substances Over the Internet, 66 Fed. Reg. 82, 21181, 21883 (April 27, 2001) (Clarifying that "[c]ompleting a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship.")

<sup>6</sup> U.S. Food and Drug Administration, Is It Legal For Me to Personally Import Drugs? <http://www.fda.gov/aboutFDA/Transparency/Basics/ucm194904.htm>.

<sup>7</sup> See e.g. <http://www.canadadrugsonline.com/faq.aspx> (citing the 90-day limitation but not the other parts of FDA's enforcement policy).

The third category of online pharmacies is the one that regulators find most troublesome: the “pill mill.” “Pill mills,” which outnumber the other types of online pharmacies,<sup>8</sup> do not pretend to know or comply with the laws of any country. In fact, these pharmacies sometimes emphasize non-compliance with the law by disguising credit card transactions and packaging, and by openly advertising non-compliant features, such as selling prescription drugs and controlled substances without a valid prescription,<sup>9</sup> or providing discounts for bulk purchases of prescription drugs.<sup>10</sup> Deputy Assistant Administrator in the Drug Enforcement Administration, Joseph Rannazzisi, summarizes the challenge of rogue pharmacies:

[T]he Internet has provided drug trafficking organizations with the perfect medium. It connects individuals from anywhere in the globe at any time; it provides anonymity; and it can be deployed from almost anywhere with very little formal training. All of these features allow for a more rapid means of diverting larger and larger quantities of controlled substances. The proliferation of rogue Internet pharmacies has also brought new legal challenges.<sup>11</sup>

The business model of a “pill mill” is founded on anonymity. The World Wide Web allows a Belgian operator to reside in Costa Rica, host websites on U.S. servers, maintain a call center in the Philippines, and sell to the U.S. market.<sup>12</sup> Worse yet, the website operator may have no

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<sup>8</sup> CASA *supra*, note 3.

<sup>9</sup> See e.g. <http://www.cialiswithoutaprescription.com>.

<sup>10</sup> See e.g. <http://www.viagrabulk.com>.

<sup>11</sup> Rogue Online Pharmacies: the Growing Problem of Internet Drug Trafficking: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (2007), (testimony of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, U.S. Drug Enforcement Admin.), available at <http://www.gpo.gov/fdsys/pkg/CHRG-110shrg43987/pdf/CHRG-110shrg43987.pdf>.

<sup>12</sup> The example is not a hypothetical: SafeMedicines.org, Internet Pharmacy Owner Pleads Guilty To Selling Fake Drugs In US Court, January 2011, <http://www.safemedicines.org/2011/01/Internet-pharmacy-owner-pleads-guilty-to-selling-fake-drugs-in-us-court-134.html>.



permanent residence at all, and operate not one, but dozens of sites hosted in different countries. According to one study, 67% of non-VIPPS accredited online pharmacies use masked registrant service to conceal their actual location and contact details.<sup>13</sup> Many “pill mill” operators do not even bother to conceal their registration information, but register using fake identification instead.<sup>14</sup>

Experienced “pill mill” operators utilize sophisticated web-design techniques to build effective hierarchies to support their business. At a given time, a “pill mill” operator may operate multiple advertising websites as well as sales websites. An operator may set up an automatic “reincarnation” response in case a website is shut down by the domain name host, to upload another template of the website to a different location and update the links on its advertising websites. For the user who enters ‘hydrocodone without prescription’ into the Google search engine, this switch in domain names would go unnoticed. “Pill mill” operators also rely on advanced advertising techniques, such as search engine optimization<sup>15</sup> and Web 2.0<sup>16</sup> content. A “pill mill” operator may spam blogs with links to his ‘pill mill,’ or incorporate popular drug

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<sup>13</sup> OpSec Security, Assessing the Risk of Counterfeit Pharmaceuticals in the Online Marketplace, 2009, available at [http://www.securingspharma.com/agile\\_assets/79/OpSec\\_Study\\_Assessing\\_the\\_Risk\\_of\\_Counterfeit\\_Pharmaceuticals\\_in\\_the\\_Online\\_Marketplace\\_wcl.pdf](http://www.securingspharma.com/agile_assets/79/OpSec_Study_Assessing_the_Risk_of_Counterfeit_Pharmaceuticals_in_the_Online_Marketplace_wcl.pdf).

<sup>14</sup> Id.

<sup>15</sup> Search engine optimization is the tweaking of a website to improve its search engine result rank for specific terms through the use of particular design and content.

<sup>16</sup> ‘Web 2.0’ is a term that describes websites where a significant portion of the content is submitted by users rather than the website operator, and includes many popular websites such as YouTube and Twitter.

names in his site. The operator may promote the “pill mill” directly on Facebook and Twitter,<sup>17</sup> or promote an “educational” video about “online prescribing” on YouTube.<sup>18</sup>

Any effort to regulate Internet pharmacies must consider these three main segments of the market to be effective. The proper measures to regulate the rare legitimate pharmacies differ from the measures necessary to highlight and eliminate “pill mills,” for instance.

### ***b. Benefits***

There are several benefits to purchasing medicine online. First, purchasing online is physically easier than going to the drugstore. For the elderly—the age group that spends most on drugs<sup>19</sup>—the consideration is an important one.<sup>20</sup> Second, the Internet as a medium offers modern medical care tools such as email reminders, comprehensive information about medicines, and 24-hour assistance. Third, online pharmacies allow patients to purchase drugs discreetly without a face-to-face interaction. Finally, the rise of online pharmacies creates more supply options for the patient to find the optimal service and price.<sup>21</sup> These benefits contributed to the growth of the legal Internet pharmacies.

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<sup>17</sup> The Partnership for Safe Medicines, *Rogue Pharmacies Using Facebook To Hook Victims*, May 2011, <http://www.safemedicines.org/2011/05/rogue-pharmacies-using-facebook-to-hook-victims-235.html>.

<sup>18</sup> See e.g. <http://www.youtube.com/watch?v=C50XXE8uuOk> (a video titled “Tips for Buying Viagra Online Without Prescription”).

<sup>19</sup> Rand Corporation, *Prescription Drugs and the Elderly: Policy Implications of Medicare Coverage*, 1999, [http://www.rand.org/pubs/research\\_briefs/RB5028/index1.html](http://www.rand.org/pubs/research_briefs/RB5028/index1.html).

<sup>20</sup> See Williams, *On-Line Prescriptions and Drug Sales: An Overview of Emerging Issues*, 1 *Hous. J. Health L. & Policy* 147 (2001).

<sup>21</sup> For example, <http://www.pharmacychecker.com> provides price comparisons for popular prescription drugs online.

### *c. Risks*

Online pharmacies also present several risks unique to the Internet medium. One risk is that a patient may receive a prescription drug based on an online questionnaire instead of a valid prescription, and suffer serious side effects or dangerous drug interactions as a result. This is the most common risk, as over 90% of online pharmacies do not require a valid prescription when selling prescription drugs<sup>22</sup> and over 95% lack appropriate licenses to sell prescription drugs in the countries to which they market their products.<sup>23</sup> Neither do online pharmacies attempt to mitigate the lack of a valid prescription by properly labeling the prescription medications – about 50% of online drugs are delivered without any information for the patient.<sup>24</sup> Another risk is that a patient may receive counterfeit drugs that are sub- or super-potent, or that are adulterated. Counterfeit drugs are manufactured, packaged, and distributed without the regulatory oversight and control exercised over genuine drugs. Counterfeit drugs have also become increasingly common worldwide, and now comprise 50% of all drugs sold online.<sup>25</sup> The third major risk of purchasing drugs from an online pharmacy is the misuse of patient medical, financial, and electronic information. Because the operators of rogue online pharmacies maintain anonymity in

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<sup>22</sup> European Alliance for Access to Safe Medicines, *The Counterfeiting Superhighway*, 2008, available at [http://v35.pixelcms.com/ams/assets/312296678531/455\\_EAASM\\_counterfeiting%20report\\_020608.pdf](http://v35.pixelcms.com/ams/assets/312296678531/455_EAASM_counterfeiting%20report_020608.pdf).

<sup>23</sup> *Id.* at 20.

<sup>24</sup> *Id.* at 28.

<sup>25</sup> See World Health Organization, *WHO and Partners Accelerate Fight Against Counterfeit Medicines*, November 2006, <http://www.who.int/mediacentre/news/releases/2006/pr69/en/index.html>.

conducting business,<sup>26</sup> they may use the established veil to steal, sell, or otherwise abuse the medical and financial information entered by the patient.<sup>27</sup>

The Internet not only creates new risks, but also substantially exacerbates the existing diversion of controlled substances. In the words of the Drug Enforcement Administration (DEA),

[w]hile in-person ‘prescription mills’ (practitioners’ offices that readily supply drug seekers with prescriptions for controlled substances without establishing a legitimate medical basis for doing so) have always been, and remain, a significant source of diversion, the advent of rogue Web sites that cater to those who abuse pharmaceutical controlled substances has allowed the criminal operators of these sites to exploit the anonymity of the Internet to generate illicit sales of controlled substances (and/or prescriptions therefor) that far exceed those of any in-person prescription mill.”<sup>28</sup>

One example of the Internet’s role in fueling the sales of controlled substances is the sales of hydrocodone, the most widely abused pharmaceutical controlled substance in the U.S.

According to the DEA, in 2006, Internet pharmacies averaged 2.9 units sold per pharmacy, compared to 88,000 units per average U.S. pharmacy.<sup>29</sup>

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<sup>26</sup> LegitScript Blog, Industry Trends: EvaPharmacy, 33Drugs (DrugRevenue) emerge as major Internet threats, October 22, 2009, <http://legitscriptblog.com/2009/10/industry-trends-evapharmacy-33drugs-drugrevenue-emerge-as-major-Internet-threats/>.

<sup>27</sup> For a full discussion on the risk that the rogue Internet pharmacies create for privacy see Jeff Karberg, Progress In the Challenge to Regulate Online Pharmacies, 23 J.L. & Health 113, 134-135 (2010).

<sup>28</sup> Department of Justice, Drug Enforcement Administration, Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008; Final Rule, 74 Fed. Reg. 15596-15625, 15597 (April 6, 2009), available at [http://www.deadiversion.usdoj.gov/fed\\_regs/rules/2009/fr0406.pdf](http://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf).

<sup>29</sup> Id.

### 3) CURRENT REGULATION

As drug sales shifted to the Internet, private organizations, Internet intermediaries, states, and the federal government, all experimented in curtailing the illegal sales. Over time, the coordination of efforts proved most effective.

#### *a. Industry groups*

Pharmacies and their trade organizations have long sought to shield their market from rogue online pharmacies, protecting consumers in the process. In 1999, the National Association of Boards of Pharmacy (NABP) developed the Verified Internet Pharmacy Practice Sites (VIPPS) program “in order to provide a means for the public to distinguish between legitimate and illegitimate online pharmacy practice sites.”<sup>30</sup> The program issues certifications to those online pharmacies that fulfill NABP’s criteria, and publishes the list of certified online pharmacies on its website. The VIPPS criteria cover standards for licensure and policy maintenance, valid prescriptions, handling of patient information, communication with patients and professionals, storage and shipment of drugs, quality improvement programs, and reporting to NABP.<sup>31</sup> Currently, there are 29 Internet pharmacies with VIPPS accreditation.<sup>32</sup>

The self-regulation by the passive accreditation system has been largely incapable of stopping the proliferation of rogue Internet pharmacies or effectively educating the public. The VIPPS

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<sup>30</sup> National Association of Boards of Pharmacy, VIPPS FAQs, <http://www.nabp.net/programs/accreditation/vipps/vipps-faqs/>.

<sup>31</sup> National Association of Boards of Pharmacy, VIPPS Criteria, available at <http://www.nabp.net/programs/accreditation/vipps/vipps-criteria/>.

<sup>32</sup> National Association of Boards of Pharmacy, Find a VIPPS Online Pharmacy, <http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy/>.

website is helpful for consumers who already value safety above price and availability, and who are informed enough to find the VIPPS website first. The average consumer may be tricked by a stolen VIPPS seal at a rogue online pharmacy website. Moreover, consumers who are interested in a drug without prescription, or in a lower price for a drug manufactured elsewhere, are not affected by the VIPPS program.

### ***b. Intermediaries***

Self-regulation by private companies extends beyond NABP, to the intermediaries who often profit from dealing with online pharmacies: financial intermediaries, search engines, advertising companies, domain name servers, and others. Because of their broad reach and function, Internet intermediaries have always balanced their own interests with the interests of various nations, consumers, and businesses. For the same reason, Internet intermediaries are targeted by both litigators and regulators.<sup>33</sup> After all, every rogue pharmacy must have a domain name, an IP address, a name server, a payment processor, and a delivery service. Rogue pharmacies present a difficult dilemma for intermediaries, because rogue pharmacies are illegal in most, but not all, developed nations, and because rogue pharmacies are profitable partners.

The self-regulation policies of Internet intermediaries are guided by two federal laws that affect the liability of intermediaries online: the Digital Millennium Copyright Act<sup>34</sup> (DMCA) and the Communications Decency Act<sup>35</sup> (CDA).

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<sup>33</sup> See Seth Kreimer, *Censorship by Proxy: The First Amendment, Internet Intermediaries, and the Problem of the Weakest Link*, 155 U. PA. L. Rev. 11, 16 (2006).

<sup>34</sup> Pub. L. 105-304 (1998).

<sup>35</sup> Pub. L. 104-104 (1996).

Section 230 of the CDA<sup>36</sup> immunizes the providers of interactive computer services<sup>37</sup> from liability as speakers or publishers of information “provided by another information content provider.”<sup>38</sup> While a useful shield against tort claims, the CDA does not apply to criminal charges, intellectual property claims, or privacy laws.<sup>39</sup> In determining the application of the CDA’s immunity, courts ask whether (1) the defendant is a provider or user of an interactive computer service; (2) the defendant is being treated as the publisher or speaker for liability purposes; and (3) the challenged information is provided by another information content provider.<sup>40</sup> The CDA applies to relationships between certain Internet intermediaries and rogue pharmacies that cause private injury to users. For example, if a user searches for a drug online using a search engine, clicks on one of the results, submits financial information, and then gets illegally charged by the rogue pharmacy, the CDA protects the search engine from fraud liability as a publisher. The CDA avoids “chilling” communication transmitted by intermediaries, but does not provide an incentive for conduit intermediaries to monitor content.

The DMCA establishes protections for online intermediaries from primary and secondary copyright liability. Section 512 of the Act<sup>41</sup> extends protection to intermediaries by type, while

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<sup>36</sup> 47 U.S.C. § 230.

<sup>37</sup> The CDA defines an “interactive computer service” as “any information service, system, or access software provider that provides or enables computer access by multiple users to a computer server.” 47 U.S.C. § 230(f)(2). This includes online intermediaries, such as search engines and other user-based websites. See e.g. *Fair Hous. Council of San Fernando Valley v. Roommates.Com, LLC*, 521 F.3d 1157 (9th Cir. 2008) (a website that facilitates user communication for matching roommates is an “interactive computer service” under the CDA).

<sup>38</sup> 47 U.S.C. § 230(c)(1).

<sup>39</sup> See 47 U.S.C. § 230(e).

<sup>40</sup> See e.g. *word Doe v. GTE Corp.*, 347 F.3d 655 (7th Cir. 2003).

<sup>41</sup> 17 U.S.C. § 512, also known as the Online Copyright Infringement Liability Limitation Act.

attaching appropriate requirements for each type of intermediary. The DMCA protects “passive” intermediaries, which transmit information automatically serving as a mere conduit, so long as the intermediary does not modify or cache the information.<sup>42</sup> Those intermediaries that temporarily cache the information for faster access are protected as well so long as they do not interfere with reasonable copy protection systems.<sup>43</sup> If the cached material is available to end users, the protection of the DMCA is available to the intermediary if the intermediary has established a process to expeditiously respond to copyright infringement claims.<sup>44</sup> Finally, those intermediaries that store (rather than temporarily cache) user material that is available to end users are eligible for the DMCA’s protection only if they satisfy three conditions: (1) the intermediary has no knowledge of the infringing material; (2) the intermediary does not receive a financial benefit from the infringing material; and (3) upon notification, the intermediary responds expeditiously to remove the infringing material.<sup>45</sup> In the context of rogue pharmacies, the DMCA provides protection from secondary copyright infringement to all “passive” intermediaries (e.g. Internet Service Providers), those cache-based intermediaries who comply with infringement requests (e.g. Domain Name Servers), and content-storing intermediaries that do not profit from infringing material, and remove the material upon notice (e.g. YouTube). For example, if Google is sued for secondary copyright infringement based on one of the search results, Google may invoke the DMCA protections for cache-based intermediaries under Section 512(b).<sup>46</sup>

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<sup>42</sup> 17 U.S.C. § 512(a).

<sup>43</sup> 17 U.S.C. § 512(b)(1).

<sup>44</sup> 17 U.S.C. § 512(b)(2)(E).

<sup>45</sup> 17 U.S.C. § 512(c)(1).

<sup>46</sup> 17 U.S.C. § 512(b).



The effect of the CDA and the DMCA protections is evident among all major intermediaries. Content-based intermediaries have established procedures to address notices of illegal posts in order to qualify for the safe harbors under the Digital Millennium Copyright Act.<sup>47</sup> On the other hand, most “passive” intermediaries exercise less gatekeeping for transmitting information.<sup>48</sup> Generally, the private measures taken by online intermediaries incorporate the statutory safeguards, except where the intermediaries are explicitly avoiding U.S. regulation and enforcement.<sup>49</sup>

### **i. Financial intermediaries**

Financial intermediaries are one of the crucial lifelines in Internet commerce for several reasons. First, financial institutions require non-anonymous contact, often including a physical address and a state-issued identification. As a result, financial intermediaries carry higher responsibility for the actions of their users, allowing the intermediaries to impose their own conditions of use and reporting the identities of the users if needed. Second, although the market for financial online intermediaries is active, a handful of companies dominate the vast majority of the market. Nearly every payment online will at some point rely on one of the few major credit card providers. Finally, the major online financial intermediaries are not easily replaceable by rogue-friendly alternatives. Consumers may follow a link that does not look completely safe, but they

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<sup>47</sup> See e.g. Craigslist Terms of Use, <http://www.craigslist.org/about/terms.of.use>; YouTube Community Guidelines, [http://www.youtube.com/t/community\\_guidelines](http://www.youtube.com/t/community_guidelines); Facebook, Report Abuse or Policy Violations, <http://www.facebook.com/help/?page=178608028874393&ref=hcnv>.

<sup>48</sup> See e.g. Saul Hansell, Hollywood Wants Internet Providers to Block Copyrighted Files, New York Times, September 25, 2008.

<sup>49</sup> See e.g. LegitScript, Internet.bs: A Safe Haven for Drug-Related Cybercrime?, March 2012, [http://www.legitscript.com/download/LegitScript\\_Report\\_on\\_Internet-bs\\_%28Large%29.pdf](http://www.legitscript.com/download/LegitScript_Report_on_Internet-bs_%28Large%29.pdf).

are more hesitant to submit financial information to a fringe payment provider, whether a bank or a payment service.<sup>50</sup>

The major credit card companies have cooperated most actively in efforts to purge their client lists from rogue pharmacies. The two major credit card companies, Visa and MasterCard, currently employ a screening policy for merchants and transactions to weed out merchants who use the payment systems for illegal sales of prescription drugs.<sup>51</sup> The companies developed their policies under the guidance of FDA and DEA in 2004-2005. Both notified their member financial institutions regarding FDA's standards for dispensing prescription drugs online. In responding to the agencies' rogue pharmacy leads in the past, the companies "worked to investigate these pharmacies and to terminate the acceptance of [the credit cards] for illicit activity."<sup>52</sup>

Smaller financial intermediaries on the Internet do not cooperate as readily. Internet "wallets,"<sup>53</sup> payment service providers,<sup>54</sup> and other payment intermediaries often serve as added middlemen

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<sup>50</sup> For empirical research showing mistrust of online payments see MODASolutions, A Look At How Online Bill Payment Changes the eCommerce Landscape, September 2007, <http://www.ebillme.com/pdfs/white-papers/ebillme-online-bill-pay.pdf> (citing Forrester Research, March 2005).

<sup>51</sup> Safety of Imported Pharmaceuticals: Strengthening Efforts to Combat the Sales of Controlled Substances over the Internet: Hearing Before the Subcommittee on Oversight and Investigations of the H. Committee on Energy and Commerce, 109th Cong. 174-76 (2005) (statements of Mark MacCarthy, Senior Vice President, Public Policy, VISA, U.S.A., Inc. and Michael McEnaney [for MasterCard], Partner, Sidley, Austin, Brown, & Wood, LLP).

<sup>52</sup> Id. (statement of Mark MacCarthy).

<sup>53</sup> An online wallet is a web service that allows users to store and control their financial information, such as a bank account number, shipping address and credit card details. Popular ones include PayPal, Amazon Payments, and Yahoo! Wallet.

for rogue pharmacies, providing additional anonymity for both the website operator and the customers. Unlike the major credit card companies and banks, smaller financial intermediaries often form outside the U.S. and derive all of their business from e-commerce, where rogue pharmacies are both profitable and willing to pay higher fees.<sup>55</sup> In fact, several payment-processing companies cater to rogue pharmacies by presenting themselves as an additional anonymity buffer in the payment chain.<sup>56</sup> The lower cooperation of smaller intermediaries may serve as a red flag in identifying rogue pharmacies.

## **ii. Search engines and advertising companies**

Internet search engines are the most commonly-used intermediaries online. Google is not only the most popular online search engine but also the most visited website globally.<sup>57</sup> Unlike other intermediaries, search engines exercise little direct control over their content, leaving it instead to a complex computer algorithm, which sorts results by numerous factors, including hyperlinks

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<sup>54</sup> A payment service provider offers website operators online services for accepting electronic payments by a variety of payment methods, such as credit card and direct debit. Advanced payment service providers provide full payment systems, including cash payments, prepaid cards or vouchers, and even paper or e-check processing. Popular payment service providers include PayPal, Authorize.net, and Moneybookers.

<sup>55</sup> The National Association of Criminal Defense Lawyers, *Champion Magazine*, Internet Pharmacy: Gray Area With Big Profit And High Risks, December 2005, available at <http://www.nacdl.org/public.nsf/698c98dd101a846085256eb400500c01/87e08fff3788cc8585257108005f68f0?OpenDocument>.

<sup>56</sup> See e.g. <http://www.offshorepaymentprocessing.com/FAQ.html> (listing the following as ‘high risk merchants’ that would benefit from offshore payment processing: adult service providers, pharmaceutical merchants, terminated merchant file accounts). See also <http://www.intabill.com/> (advertising for pharmaceuticals and gambling websites on the front page.)

<sup>57</sup> Alexa, Top Sites, <http://www.alexa.com/topsites>.

between websites, overall popularity, and page-specific content.<sup>58</sup> Search engines add content to their vast databases through “web crawling” by Internet robots, followed by automatic indexing. Depending on the prompt, a search engine may provide a custom result that is not part of the computer algorithm. For instance, Google may provide a direct (rather than hyperlinked) answer to the prompt “what is the weather in New York?” In the context of medicines, where a prompt comprises the name of a medication, such as “Lipitor,” Google’s first result links to the drug’s page on the National Institutes of Health website.<sup>59, 60</sup> Beyond this tweak, search engines do not manually intervene with organic search results generated by the computer algorithm.<sup>61</sup> The lack of manual intervention is seen as crucial for the integrity of search engines; but it also makes filtering more difficult. Operators of rogue pharmacies are unsurpassed in manipulating search engine results, which is why, for instance, the front page search results for “buy Lipitor” comprise nine online pharmacies, none of which is accredited by NABP or even the more lenient Legitscript.com.<sup>62, 63</sup> Despite this manipulation, the indexing process remains almost entirely

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<sup>58</sup> The Official Google Blog, Introduction to Google Ranking, July 2008, <http://googleblog.blogspot.com/2008/07/introduction-to-google-ranking.html>.

<sup>59</sup> Jesse Andrews, Google Partners with NIH, Pharma Marketing Insight by DoctorDirectory, Issue 8 (August 2010).

<sup>60</sup> Bing provides a similar modification, but linking to a different website.

<sup>61</sup> One of Google’s three ranking principles is “no manual intervention,” The Official Google Blog, Introduction to Google Ranking, July 2008. <http://googleblog.blogspot.com/2008/07/introduction-to-google-ranking.html>. Notably, however, Google sometimes removes websites from the index, where Google believes that the website may be illegal: See e.g. Google Webmaster Tools, Site removed from the Google index, November 2011, [support.google.com/webmasters/bin/answer.py?hl=en&answer=40052](http://support.google.com/webmasters/bin/answer.py?hl=en&answer=40052) (explaining that “Google may temporarily or permanently remove sites from its index and search results if it believes it is obligated to do so by law...”)

<sup>62</sup> Searched via Google on May 19, 2011. The results included the following rogue pharmacies: [www.planetdrugsdirect.com](http://www.planetdrugsdirect.com), [www.northwestpharmacy.com](http://www.northwestpharmacy.com), [www.canadadrugs.com](http://www.canadadrugs.com), [www.pharmacyescrow.com](http://www.pharmacyescrow.com),

automatic, keeping Google's monitoring a step behind; and the incentives to monitor more strictly are diminished by the CDA's immunity provision.

Search engines exercise more control when they act as advertisers, displaying relevant ads whenever a purchased "ad-word" is in the search prompt. Each major search engine features a detailed policy for advertising, restricting the advertising of several products, such as alcohol, casinos, drugs, and weapons.<sup>64</sup> In their role as advertisers, search engines collect millions of dollars in revenue, proportionally tied to the traffic that the ads generate for rogue Internet pharmacies.<sup>65</sup>

When the CDA was passed, it was not entirely clear whether the advertising services offered by search engines qualify for the immunity provisions. The question hinged on whether, when acting as advertisers, search engines contribute to user-submitted information, and thus become information content providers under Section 230. To purchase an ad through Google, a company buys certain keywords that will trigger the appearance of the ad. Google provides the company a keyword suggestion tool to identify possible keywords, based on search data. Other major

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[www.valuepharmaceuticals.com](http://www.valuepharmaceuticals.com), [www.canamericanglobal.com](http://www.canamericanglobal.com), [www.buy-lipitor.net](http://www.buy-lipitor.net), [www.canadadrugcenter.com](http://www.canadadrugcenter.com), and [www.buckadaypharmacy.com](http://www.buckadaypharmacy.com).

<sup>63</sup> Another example is the Google search for "Viagra," which returns [www.cheapviagraonline.com](http://www.cheapviagraonline.com) as one of the front page results. The website consists of one line of text (linking to another rogue pharmacy) on a white background. That the single line of text came ahead of numerous legitimate major pharmacies that legally sell Viagra attests to the skill of the website operator in manipulating search results.

<sup>64</sup> See e.g. Google Advertising Policies.

<http://support.google.com/adwordspolicy/bin/static.py?hl=en&topic=1310880&guide=1308252&page=guide.cs>

<sup>65</sup> Bryan Liang, Searching For Safety: Addressing Search Engine, Website, And Provider Accountability For Illicit Online Drug Sales, 35 Am. J.L. & Med. 125 (2009).

search engines implement similar systems. In *Goddard v. Google, Inc.*,<sup>66</sup> the court concluded that CDA’s immunization does apply to Google in its role as an advertising service, because the service was a mere framework that could be used for both legal and illegal purposes. The *Goddard* reasoning built on the analysis of *Carafano v. Metroplash*,<sup>67</sup> which granted CDA immunity to a dating website. *Carafano* established that a tool facilitating the expression of information is considered “neutral” so long as users ultimately determine what content to post.<sup>68</sup> As a result, at least in California, search engines do enjoy CDA liability protection when acting as advertisers.

Yet, the role of search engines as advertisers in facilitating rogue pharmacy traffic was untenable: the popular search engines are major U.S. corporations long subject to U.S. laws, and responsible for the vast majority of online traffic.<sup>69</sup> Moreover, while the CDA protects search engines against some claims, the Act does shield the companies from criminal prosecution. After pressure from policymakers, all three major search engines—Google, Yahoo!, and Bing—began limiting accepted pharmacy ads to those certified by PharmacyChecker, an independent evaluator of online pharmacies.<sup>70, 71</sup> However, an investigation by the FDA in 2009 revealed that

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<sup>66</sup> 640 F. Supp. 2d 1193 (N.D. Cal. 2009).

<sup>67</sup> 339 F.3d 1119 (9th Cir.2003).

<sup>68</sup> *Goddard v. Google, Inc.*, 640 F. Supp. 2d 1193, 1197 (N.D. Cal. 2009).

<sup>69</sup> See Feng Qiu, Zhenyu Liu, Junghoo Cho, Analysis of User Web Traffic with a Focus on Search Activities, available at <http://oak.cs.ucla.edu/~cho/papers/qiu-user.pdf>.

<sup>70</sup> See Internet Drug Sales: Hearings before the H.R. Committee on Government Reform, 104th Congress. (2004) (Statement of William K. Hubbard, Associate FDA Commissioner for Policy and Planning); Thomas Catan, Amir Efrati, Google Was Warned on Rogue Drug Ads, Wall Street Journal, May 21, 2011.

<sup>71</sup> Google also relied on the company Square Trade. See Claire Cain Miller, Google Reaches \$500 Million Settlement With Government, New York Times, August 24, 2011.

the self-regulation was insufficient on both ends – rogue pharmacies slipped through the cracks of both Google AdWords and PharmacyChecker ([www.pharmacychecker.com](http://www.pharmacychecker.com)).<sup>72</sup> Scrambling to tighten its admission criteria, Google agreed to settle the investigation for \$500 million, and sacked PharmacyChecker for NABP’s VIPPS.<sup>73</sup> Microsoft Bing and Yahoo! followed suit.<sup>74</sup> The Department of Justice later revealed that the prosecution against Google’s AdWords was built around the Food, Drug and Cosmetic Act and the Controlled Substances Act, both of which provide criminal penalties for offenders.<sup>75</sup>

Google’s failure to keep rogue pharmacies off its advertising client list—whether through incompetence or convenience—raises the question of the necessary government regulation in the area. Although the VIPPS is unlikely to lose its “gold standard” criteria for admission, Google’s semi-automatic AdWords system has allowed the participation of uncertified rogue pharmacies in the past. The \$500 million paid to settle the investigation is insubstantial considering the \$1 billion-a-year revenues from online pharmacy ads.<sup>76</sup> Taken together, the profitability of AdWords advertising, the control that search engines have exercised over advertising, and the search engines’ patchy past in self-regulation of advertising led some commentators to call for increased regulation of search engines’ advertising services.<sup>77</sup>

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<sup>72</sup> Thomas Catan, Amir Efrati, Google Was Warned on Rogue Drug Ads, Wall Street Journal, May 21, 2011.

<sup>73</sup> Id.

<sup>74</sup> Id.

<sup>75</sup> Department of Justice, Google Forfeits \$500 Million Generated by Online Ads & Prescription Drug Sales by Canadian Online Pharmacies, Press Release, August 24, 2011, available at <http://www.justice.gov/opa/pr/2011/August/11-dag-1078.html>.

<sup>76</sup> Id.

<sup>77</sup> See Id.

### **iii. Domain name registrars**

Despite the appearance of anarchy, the Internet maintains a system of rules developed by the Internet Corporation for Assigned Names and Numbers (ICANN). ICANN is responsible for accrediting domain name registrars, the companies that lend Internet addresses to website operators for a fee.<sup>78</sup> The Registrar Accreditation Agreement requires all registrars to prohibit website owners from using the registrar's leased domain names for unlawful purposes.<sup>79</sup> Yet, registrars have historically been slow and reluctant to ban and purge rogue online pharmacies. The main reasons behind lack of self-regulation is the loose registration process, which facilitates anonymity for website operators; and the ephemeral nature of rogue pharmacies, which makes the ever-emerging pharmacies a lucrative business.

Domain name registrars' ability to regulate clients is handicapped by the WhoIs registration system for the purchasers of domain names. The registration process accepts the website operator's data on an honor system, without requiring proof or validation. Unsurprisingly, a U.S. GAO report found that nearly 9% of all websites were registered with blatantly false or missing WhoIs data, such as "qwerty" for name and "123456789" for a phone number.<sup>80</sup> The 9% comprise the lazy website operators; it is unclear how many operators enter false data that looks a little more realistic. In addition to neglecting to validate registration data, registrars offer

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<sup>78</sup> For background, see KnujOn Internet Security Report: Audit of the gTLD Internet Structure, Evaluation of Contractual Compliance, and Review of Illicit Activity by Registrar – 2010, [www.knujon.com/knujon\\_audit0610.pdf](http://www.knujon.com/knujon_audit0610.pdf).

<sup>79</sup> Internet Corporation for Assigned Names and Numbers, Registrant Rights and Responsibilities Under the 2009 Registrar Accreditation Agreement, <http://www.icann.org/en/registrars/registrant-rights-responsibilities-en.htm>.

<sup>80</sup> U.S. GAO, Internet Management: Prevalence of False Contact Information for Registered Domain Names.



website operators the option of hiding the WhoIs data from the public entirely for \$10 a year.<sup>81</sup>

The option hides the identity of the operator from the public.

Besides a loose registration process and the sale of additional anonymity, many domain name registrars welcome rogue pharmacies and refuse to shut them down even upon a notice of the unlawful activity. In a study by the Internet compliance group Knujon, eleven out of sixteen registrars acted to shut down rogue pharmacies on their domains, while the other five refused to cooperate.<sup>82</sup> In response to evidence that the pharmacy certificates on the rogue websites were fake, the five registrars claimed that their responsibility as registrars does not extend to policing the operators that use their services.<sup>83</sup> Recognizing the role of registrars in the facilitation of unlawful pharmaceutical sales, the NABP has issued a letter to registrars, requesting the termination of all rogue pharmacies (pharmacies that are not approved by LegitScript), pursuant to ICANN's Uniform Domain-Name Dispute-Resolution Policy signed by each registrar.<sup>84</sup> Pressure by Knujon and CastleCops finally persuaded ICANN to exercise its authority and shut down one of the offending registrars (the owner of which was convicted of credit card fraud,

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<sup>81</sup> See e.g. GoDaddy, Private Domain Registration, <http://www.godaddy.com/domainaddon/private-registration.aspx>. GoDaddy is the largest accredited registrar.

<sup>82</sup> LegitScript and Knujon, Rogues and Registrars: Are some Domain Name Registrars safe havens for Internet drug rings?, 2010, <http://legitscriptblog.com/download/Rogues-and-Registrars-Report.pdf>.

<sup>83</sup> Id.

<sup>84</sup> NABP Letter to Domain Name Registrar, 2/10/2011, [http://www.legitscript.com/download/DNR-letter\\_10Feb2011.pdf](http://www.legitscript.com/download/DNR-letter_10Feb2011.pdf).

money laundering, and document forgery in Estonia).<sup>85</sup> The decision to terminate the registrar resulted in the diaspora of hundreds of thousands of websites, both legitimate and unlawful.<sup>86</sup> In sum, domain name registrars provide minimal self-regulation against rogue pharmacies. ICANN largely held back its authority to terminate whole registrars, as the shotgun measure often hurts legal websites more than unlawful ones. The lack of cases concerning prosecution of domain name registrars for refusing to monitor their clientele indicates one of two conclusions: either regulators are hesitant to prosecute registrars given the existing scant law, or the registrars are more compliant with regulators than with private organizations, or both. Either way, the structure of domain name registrars suggests that these intermediaries, while necessary for Internet pharmacies (and all other websites), are too blunt of a regulatory target.

#### **iv. Other intermediaries**

Several major websites, such as eBay, Amazon, Craigslist, YouTube, and Facebook, rely on user-generated input, leaving an open door for user-generated advertising of rogue pharmaceutical websites. These other website intermediaries comprise mainstream websites (e.g. YouTube) and fringe websites (e.g. forums on importing medicine). The mainstream intermediaries offer wide exposure whereas the fringe websites are better at attracting and “converting” repeat visitors.<sup>87</sup> The mainstream content-based intermediaries have all established

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<sup>85</sup> ICANN Letter to Vladimir Tsastsin, President of ESTDomains, Inc., Re: Notice of Termination of ICANN Registrar Accreditation Agreement, October 28, 2008.

<sup>86</sup> See LegitScript Blog, ICANN terminates Domain Name Registrar Sponsoring Rogue Internet Pharmacies, October 29, 2008, <http://legitscriptblog.com/2008/10/icann-terminates-domain-name-registrar-sponsoring-rogue-Internet-pharmacies>.

<sup>87</sup> See CASA, *supra* note 3

procedures to address notices of illegal posts in order to qualify for the safe harbors under the DMCA and the CDA.<sup>88</sup> However, fringe intermediaries, such as forums and ad-sites<sup>89</sup> are more fragmented and less compliant. A typical search for a prescription medicine returns several ad-sites whose sole purpose is to bridge the user to a rogue pharmacy. Although these fringe intermediaries generate little traffic on their own, they are potent tools at evading the filters of other larger intermediaries to reach the Internet users. Besides avoiding self-regulation, fringe intermediaries also pose regulatory challenges to the U.S. agencies.

### *c. States*

The regulation of pharmacies and physicians traditionally belongs to the states. State laws limit dispensing of prescription drug to (1) licensed pharmacists working in (2) licensed pharmacies, and only upon the presentation of a (3) valid prescription from a (4) licensed health care professional.<sup>90</sup> State boards of pharmacy establish and enforce the operation standards for pharmacies within each state. State boards of pharmacy also issue licenses to pharmacies and pharmacists, and most issue licenses to out-of-state pharmacies that sell drugs to residents of the state. Conversely, state medical boards license health care professionals and outline the practice of medicine standards, including the requirements for a valid prescription. The regulation by the two types of boards is integrated with state law. For instance, in a number of states, medical

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<sup>88</sup> See e.g. Craigslist Terms of Use, <http://www.craigslist.org/about/terms.of.use>; YouTube Community Guidelines, [http://www.youtube.com/t/community\\_guidelines](http://www.youtube.com/t/community_guidelines); Facebook, Report Abuse or Policy Violations, <http://www.facebook.com/help/?page=178608028874393&ref=hcnv>.

<sup>89</sup> An ad-site is a website whose whole purpose is to advertise and link to another website.

<sup>90</sup> U.S. General Accounting Office, Internet Pharmacies: Some Pose Safety Risks to Consumers, GAO-04-820, 2004, available at <http://www.gao.gov/new.items/d04820.pdf>.

boards define invalid prescribing as “unprofessional conduct,” and state laws allow penalties for physicians who engage in unprofessional conduct.<sup>91</sup> The state or the professional boards may take action against a pharmacy, a pharmacist, or a health care professional, based on the violation of any of the four criteria for prescribing medications. In the context of online pharmacies, the relevant state requirement is the issuance and acceptance of a valid prescription.

Initially, states relied on the existing licensing and consumer protection regulations.<sup>92</sup> The first multi-state response was the creation of the Online Pharmacy Working Group by the National Association of Attorneys General (NAAG), to share information on rogue online pharmacies.<sup>93</sup>

As the number of rogue online pharmacies continued to grow, many states passed policy statements or interpretations, to clarify that state laws apply to online pharmacies as well.<sup>94</sup>

Several states have passed laws to ban online prescription, some by listing in-person evaluation as a requirement for a valid prescription, while others by explicitly banning prescriptions by Internet.<sup>95</sup> Today, only five states do not address Internet prescribing through regulation.<sup>96</sup> Most

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<sup>91</sup> See e.g. Cal. Bus. & Prof. Code § 4607, Louisiana State Board of Medical Examiners, Statement of Position: Internet/Telephonic Prescribing, May 2000.

<sup>92</sup> See e.g. State Files Consumer Fraud Charges Against Eight Online Pharmacies, BNA Health L. Rep., Apr. 6, 2000, at 503 (describing New Jersey’s prosecution policies against rogue online pharmacies); BNA Health L. Rep., Jan 20, 2000, at 92 (describing an agreement between Michigan and online pharmacies to cease sales to Michigan residents).

<sup>93</sup> See Hearings Before the Subcomm. on Oversight and Investigations of the House Comm., 106th Cong. (2000) (statement of Carla J. Stovall, Kansas Attorney General).

<sup>94</sup> See Federation of State Medical Boards, Internet Prescribing – State Medical Board Policies/State Legislation, 2008, [http://www.fsmb.org/pdf/SMB\\_Policies-State\\_Laws\\_INTERNET.pdf](http://www.fsmb.org/pdf/SMB_Policies-State_Laws_INTERNET.pdf).

<sup>95</sup> See Federation of State Medical Boards, *supra* note 4.

<sup>96</sup> *Id.*

of the regulations are promulgated by the boards of medicine, and range from direct regulation of Internet prescriptions<sup>97</sup> to general requirements that the physician examine the patient for a prescription to be considered valid.<sup>98</sup> The Federation of State Medical Boards (FSMB), a nonprofit organization providing guidance to state boards of pharmacy and medical boards, took the early position that “[t]reatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.”<sup>99</sup> The American Medical Association adopted a similar policy, finding Internet prescribing “below a minimum standard of medical care.”<sup>100</sup> States have also begun enforcing their licensing privileges by prohibiting the sales of pharmaceuticals into the state by unlicensed online pharmacies.<sup>101</sup>

Despite the promulgation of new laws, their enforcement against most Internet pharmacies, and especially “pill mills,” has been a difficult challenge for the states. State boards of pharmacy and medicine struggle to identify pharmacy owners and prescribing physicians, and to dedicate sufficient resources to prosecute violators.<sup>102</sup> As with online gambling and copyright violations,

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<sup>97</sup> See e.g. Massachusetts Board of Registration in Medicine, Prescribing Practices Policy and Guidelines, August 1 1989, amended December 12, 2001, available at <http://www.massmedboard.org/regs/pdf/prescribe2.pdf>.

<sup>98</sup> See e.g. Ariz. Rev. Stat. Ann. § 32-1854.

<sup>99</sup> Federation of State Medical Boards, Model Guidelines for the Appropriate Use of the Internet in Medical Practice, April 2002, available at [http://www.fsmb.org/pdf/2002\\_grpol\\_Use\\_of\\_Internet.pdf](http://www.fsmb.org/pdf/2002_grpol_Use_of_Internet.pdf).

<sup>100</sup> American Medical Association, Report of the Board of Trustees, Subj: Internet Prescribing, 35-A-99, 1999, available at

<http://www.ama-assn.org/meetings/public/annual99/reports/onsite/bot/rtf/bot35.rtf>.

<sup>101</sup> See Federation of State Medical Boards, *supra* note 4.

<sup>102</sup> U.S. General Accounting Office, Internet Pharmacies: Some Pose Safety Risks to Consumers, GAO-04-820, 2004.

the global nature of the Internet often does not lend itself to effective regulation by the states. The NAAG recognized the limitations of the states in dealing with Internet pharmacies when the organization formally requested for federal legislation that would grant the states the power to seek nation-wide injunctive relief against rogue Internet pharmacies.<sup>103</sup> The states are best situated to investigate diversion once it occurs in their borders, but not to prevent it on the World Wide Web.

#### ***d. Federal***

On the federal level, the introduction of drugs into interstate commerce is subject to the Federal Food, Drug, and Cosmetic Act (FDCA), enforced by the Food and Drug Administration (FDA). Drugs classified as controlled substances are also subject to the Controlled Substances Act (CSA), enforced by the Drug Enforcement Administration (DEA). Where Internet pharmacies engage in “deceptive or unfair practices in commerce,” the Federal Trade Commission (FTC) has assisted FDA investigations under the Federal Trade Commission Act. However, the FTC considers the regulation of Internet pharmacies to be mainly the responsibility of the FDA.<sup>104</sup>

#### **i. The Food, Drug, and Cosmetic Act**

The FDCA prohibits the “introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.”<sup>105</sup> Generally, the FDCA defines drugs

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<sup>103</sup> See Hearings Before the Subcomm. on Oversight and Investigations of the House Comm., 106th Cong. (2000) (statement of Carla J. Stovall, Kansas Attorney General).

<sup>104</sup> Working Agreement Between FTC and FDA, 4 Trade Reg. Rep. (CCH) ¶ 9,851 (1971) (establishing the basic division of responsibilities between the FDA and the FTC).

<sup>105</sup> 21 U.S.C. § 331(a).

‘adulterated’ if their manufacture is non-compliant with published manufacturing practices or if their composition differs from the published standard or is unsafe.<sup>106</sup> The FDCA defines drugs ‘misbranded’ if their labeling is false or misleading, or lacks any of the information that the FDCA requires to be placed on the label.<sup>107</sup> Finally, the FDCA prohibits the dispensation of a prescription drug under the FDCA, except upon a written prescription by a licensed practitioner.<sup>108</sup>

Several cases discuss the definition of a “valid prescription” under the FDCA. The Supreme Court first discussed the definition of a prescription in the context of the Harrison Narcotic Act of 1914, ruling that (1) a prescription may only be issued for legitimate medical purposes pursuant to a valid doctor-patient relationship;<sup>109</sup> and (2) the issuance of prescription without a doctor-patient relationship violates the “professional practice” standard.<sup>110</sup> Later Circuit Court opinions adopted the Supreme Court’s view of the definition in the Harrison Narcotic Act to interpret the prescription requirement in the FDCA.<sup>111</sup> Today, the case law requires the following for a valid prescription: a sufficient medical examination and consideration of the patient’s individual needs, a valid doctor-patient relationship, and a good faith determination that

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<sup>106</sup> 21 U.S.C. § 351.

<sup>107</sup> 21 U.S.C. § 352.

<sup>108</sup> 21 U.S.C. § 353(b).

<sup>109</sup> *Webb v. United States*, 249 U.S. 96 (1919).

<sup>110</sup> *Jin Fuey Moy v. United States*, 254 U.S. 189 (1920)

<sup>111</sup> See e.g. *Brown v. United States*, 250 F.2d 745 (5th Cir. 1958) (additionally emphasizing the requirement of a doctor-patient relationship for a valid prescription); *White v. United States*, 399 F.2d 813 (8th Cir. 1968) (ruling that no doctor-patient relationship exists where the doctor has never met the patient, and convicting a doctor for prescribing prescription drugs outside of a doctor-patient relationship).

the medication is medically necessary.<sup>112</sup> An example of the modern standard as applied to online prescribing is the Third Circuit case *U.S. v. Nelson*.<sup>113</sup> There, the court concluded that prescribing online without a medical examination was both “without legitimate medical purpose” and outside of “the usual course of medicine.”<sup>114, 115</sup> Although the case law is helpful in prosecuting some offending websites, not all Circuit Courts had chance to interpret the prescription requirement in the context of Internet prescriptions, making it burdensome for the FDA to initiate cases relying on the prescription requirement alone.

Since the emergence of the first Internet pharmacies, the FDA has relied on the FDCA’s core provisions to investigate and prosecute Internet pharmacies that mislabel drugs, sell counterfeit or foreign-market drugs, or issue their own online prescription.<sup>116</sup> Beginning in 1996, the agency began coordinating its activities with a coalition of trade groups, including FSMB, NAAG, and AMA.<sup>117</sup> The FDA prioritized its efforts based on public risk, focusing foremost on unapproved

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<sup>112</sup> Peter B. Hutt, Richard A. Merrill, Lewis A. Grossman, *Food and Drug Law: Cases and Materials*, Ch. 4(e) (3rd ed. 2007).

<sup>113</sup> *United States v. Nelson*, 383 F.3d 1227 (10th Cir. 2004).

<sup>114</sup> *Nelson*, 383 F.3d 1227, at 1233.

<sup>115</sup> *U.S. v. Nelson* discussed the Controlled Substances Act rather than the FDCA, but its reasoning is instructive nonetheless, and no case has yet made a distinction between the valid prescription requirement under the CSA versus the requirement under the FDCA.

<sup>116</sup> See *Benefits and Risks of Online Pharmacies: Hearings before the H.R. Subcomm. on Oversight & Investigations, Comm. on Commerce.*, 106th Congress. 51, (1999) (Statement of Janet Woodcock, director of FDA’s Center for Drug Evaluation and Research).

<sup>117</sup> *Benefits and Risks of Online Pharmacies: Hearings before the H.R. Subcomm. on Oversight & Investigations, Comm. on Commerce.*, 106th Congress. 51, (1999) (Statement of Jane E. Henney, M.D., FDA Commissioner).



new drugs, but also health fraud and prescription drugs dispensed without a valid prescription.<sup>118</sup> The agency also improved its data acquisition from the Internet, coordinated case assessment between the FDA Centers, and enhanced enforcement resources.<sup>119</sup> By 2000, the FDA issued 23 warning letters to rogue Internet pharmacies based domestically and thirteen “cyber” letters to those based abroad, imposed an injunction against the sale of a thyroid-based weight-loss drug, and issued fourteen import alerts.<sup>120</sup> In 2004, the FDA relied on the cooperation of U.S.-based Internet service providers (ISPs) to shut down four foreign Internet pharmacies dealing counterfeit contraceptives.<sup>121</sup> The agency also successfully prosecuted several rogue pharmacies located within the U.S., charging the operators with conspiracies to violate the FDCA, money laundering, mail fraud, dispensing misbranded drugs, and operating unregistered drug facilities.<sup>122</sup>

The growing prevalence of rogue Internet pharmacies<sup>123</sup> puts in question the sufficiency of the FDA’s efforts. The agency has to rely on substantial voluntary cooperation of ISPs, search engines, other agencies, and foreign governments to shut down foreign-based rogue pharmacies. Recognizing its limitations, the FDA asked Congress to mandate a federal license for Internet pharmacies, similar to the licenses of brick-and-mortar pharmacies, and require each Internet

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<sup>118</sup> Id.

<sup>119</sup> Id.

<sup>120</sup> Id.

<sup>121</sup> Internet Drug Sales: Hearings before the H.R. Committee on Government Reform, 104th Congress. (2004) (Statement of William K. Hubbard, Associate FDA Commissioner for Policy and Planning).

<sup>122</sup> Id.

<sup>123</sup> See CASA

pharmacy to display its contact information on its website.<sup>124</sup> Such a proposal would maintain the states' authority over the practice of medicine and pharmacy, and require minimal federal legislation. Today, the proposal is still circulating in the U.S. Senate,<sup>125</sup> and the FDA is still employing its traditional authority to prosecute both rogue Internet pharmacies and intermediaries.<sup>126</sup>

## **ii. The Controlled Substances Act**

When Internet pharmacies sell controlled substances they become subject to the Controlled Substances Act, which defines certain drugs as “controlled substances” and lists them within one of five established schedules, depending on potential for abuse and accepted medical use.<sup>127</sup> The CSA makes it unlawful for any person to “manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance,”<sup>128</sup> allowing an exception to those who register with the Attorney General in accordance with the agency's regulations.<sup>129</sup>

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<sup>124</sup> Benefits and Risks of Online Pharmacies: Hearings before the H.R. Subcomm. on Oversight & Investigations, Comm. on Commerce., 106th Congress. 51, (1999) (Statement of Jane E. Henney, M.D., FDA Commissioner).

<sup>125</sup> Online Pharmacy Safety Act, S. 2002, 112th Congress.

<sup>126</sup> See e.g. FDA's investigation of Google, *supra* note ; see also FDA Press Release, FDA Issues 22 Warning Letters to Web Site Operators, November 19, 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm191330.htm> (issuing warning letters to rogue Internet pharmacies).

<sup>127</sup> 21 U.S.C. § 801 et. seq.

<sup>128</sup> 21 U.S.C. § 841(a)(1).

<sup>129</sup> 21 U.S.C. § 822(a)-(b).

The CSA requires a written or oral prescription for all drugs that are determined prescription drugs by the FDA.<sup>130</sup>

Prior to 2008, the DEA relied on the CSA's core provisions to trace and prosecute rogue Internet pharmacy operators. The agency examined the electronic filings of distributors and manufacturers to identify those pharmacies that prescribe unusually high proportion of controlled substances.<sup>131</sup> Because Internet pharmacies churn out many more prescriptions than brick-and-mortar pharmacies do, and because 95% of these prescriptions are for controlled substances, the DEA's high-volume leads often led to rogue Internet pharmacies.<sup>132</sup> Additionally, the agency's investigation of narcotics trafficking uncovered links to rogue Internet pharmacies as well.<sup>133</sup> The DEA also began cooperation with intermediaries and other agencies, similarly to the FDA's early efforts, aiming to use the cumulative intelligence to improve monitoring and enforcement.<sup>134</sup> Specifically, the agency conducted several education sessions for wholesale distributors to combat diversion, and established the Internet Industry Initiative "to exploit the weaknesses inherent to the schemes used by Internet traffickers who rely extensively on the commercial services of [ . . . ] Internet service providers, [delivery] companies, and financial

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<sup>130</sup> 21 U.S.C. § 829(a)-(b).

<sup>131</sup> Rogue Online Pharmacies: the Growing Problem of Internet Drug Trafficking: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (2007), (testimony of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.), available at <<http://www.gpo.gov/fdsys/pkg/CHRG-110shrg43987/pdf/CHRG-110shrg43987.pdf>>.

<sup>132</sup> Id.

<sup>133</sup> Id.

<sup>134</sup> Id. See also Hearing Before the Subcommittee on Oversight & Investigations, House Energy & Commerce Committee, 108th Cong. (December 13, 2005), (testimony of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.).

service companies.<sup>135</sup> Finally, the DEA formed a specialized section within its Special Operations Division, which began investigating multi-jurisdiction Internet pharmacies, beginning in 2004.<sup>136</sup> The section actively coordinates Internet investigations to capture perpetrators and controlled substances.

Yet, the enforcement of the CSA to shut down rogue Internet pharmacies remained a challenge for the DEA, due to limited jurisdiction, the slow pace of litigation compared to online commerce, and merely case law as authority against questionnaire pharmacies.<sup>137</sup> In the height of the advocacy campaign for additional federal legislation, President George W. Bush called on Congress to enact legislation to facilitate the regulation of rogue Internet pharmacies.<sup>138</sup> Later that year, Congress acquiesced.

## **4) MOST RECENT FEDERAL LEGISLATION: THE RYAN HAIGHT ACT**

In 2008 Congress expanded CSA to address Internet pharmacies directly by passing the Ryan Haight Online Pharmacy Consumer Protection Act (Ryan Haight Act or RHA).<sup>139</sup> In its key

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<sup>135</sup> Id.

<sup>136</sup> Id.

<sup>137</sup> See Department of Justice Oversight: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (July 18, 2006) (statement of Alberto Gonzales, former Attorney General of the United States); see also Oversight of the U.S. Department of Justice: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (Jan. 18, 2007) (response to questions for the record posed to Alberto Gonzales).

<sup>138</sup> President George W. Bush, Radio Address: 2008 National Drug Control Policy (Mar. 1, 2008), available at <http://www.whitehouse.gov/news/releases/2008/03/20080301.html>.

<sup>139</sup> Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (RHA).

provisions, the RHA requires that each online pharmacy register with the DEA for an approval to sell controlled substances online;<sup>140</sup> and prohibits prescribing over the Internet, unless a physician has conducted an in-person examination of the patient.<sup>141</sup> The Act takes the opportunity to finally define the term ‘valid prescription’ in a federal statute, as “a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by [. . .] a practitioner who has conducted at least 1 in-person medical evaluation of the patient.”<sup>142</sup> The RHA also adopts FDA’s earlier proposal and requires each online pharmacy to post its contact and registration information on the pharmacy’s homepage.<sup>143</sup>

In addition to creating explicit legal requirements for online pharmacies, RHA facilitates prosecution and deterrence by (1) increasing the penalties for distributing certain drugs;<sup>144</sup> (2) requiring each online pharmacy to report its dispensing volume to the U.S. Attorney General when the pharmacy dispenses over 5,000 dosage units monthly;<sup>145</sup> (3) prohibiting advertising or aiding illegal online sales of controlled substances;<sup>146</sup> and (4) creating a civil cause of action and an injunctive relief for state attorneys general.<sup>147</sup> These provisions indicate an understanding that legal requirements alone are insufficient in shutting down savvy “pill mills.”

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<sup>140</sup> RHA § 3(b), 21 U.S.C. § 823(f).

<sup>141</sup> RHA § 2, 21 U.S.C. § 829(e).

<sup>142</sup> RHA § 2, 21 U.S.C. § 829(e)(2)(A).

<sup>143</sup> RHA § 3(d)(1), 21 U.S.C. § 831(c).

<sup>144</sup> RHA § 3(e), 21 U.S.C. § 841(b).

<sup>145</sup> RHA § 3(c), 21 U.S.C. 827(d).

<sup>146</sup> RHA § 3(f) and (g), 21 U.S.C. § 841(h) and 21 U.S.C. § 843(c)(2).

<sup>147</sup> 21 U.S.C. § 882(c).

***a. The in-person examination requirement for a valid prescription***

The RHA's requirement that a valid prescription must be based on an in-person medical evaluation is not entirely new: prior to the enactment of the Act, the CSA listed in-person examination as one of the four recommended criteria in determining the existence of a physician-patient relationship.<sup>148</sup> The DEA has long established that a controlled substance may be prescribed only "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."<sup>149</sup> Although the terms "legitimate medical purpose" and "usual course of professional practice" are not defined in the statute, courts interpreted the term "professional practice" to refer to accepted medical practice, which requires a physician-patient relationship.<sup>150</sup> The DEA further clarified in its 2001 guidance that completing a questionnaire online is "unlikely" to form a doctor-patient,<sup>151</sup> and is thus usually insufficient for a valid prescription. The RHA takes the extra step to remove all doubt that a mere in-person examination is insufficient for a physician-patient relationship under federal law. Now federal prosecutor no longer have to rely on juries to determine whether an Internet interaction establishes a physician-patient relationship.

The significance of the new in-person medical examination is best illustrated in the case of Orlando Birbragher.<sup>152</sup> Birbragher operated a questionnaire pharmacy ("Pharmacom") to sell

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<sup>148</sup> Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 5; See also 21 C.F.R. § 1306.04(a).

<sup>149</sup> 21 C.F.R. § 1306.04(a).

<sup>150</sup> *U.S. v. Birbragher*, 603 F.3d 478 (8th Cir. 2010) (Citing *United States v. Vamos*, 797 F.2d 1146, 1151 (2d Cir. 1986)).

<sup>151</sup> Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 5.

<sup>152</sup> *U.S. v. Birbragher*, 603 F.3d 478 (8th Cir. 2010).

Schedule III and IV controlled substances to customers based on an online health history questionnaire. Pharmacom contracted with physicians to review the questionnaires, and with pharmacies to fill the orders based on the physicians' "prescriptions." On November 7, 2007, after generating over \$40 million in sales, Birbragher and other co-defendants were charged in a 31-count indictment. The main drug conspiracy charge was dispensing Schedule III and IV controlled substances outside of the usual course of professional practice and without a legitimate medical purpose, in violation of 21 U.S.C. § 841(a)(1)<sup>153</sup> and § 841(b)(1)(d).<sup>154</sup> Birbragher asserted two arguments in his defense: (1) that in 2003, when the alleged conspiracy began, CSA was unclear regarding the legality of the manner in which he dispensed controlled substances; and (2) that the fact that Congress passed the RHA establishes CSA's ambiguity concerning online questionnaires prior to the RHA.<sup>155</sup>

In rejecting Birbragher's vagueness arguments, the Eighth Circuit noted that "Birbragher has not cited any authority, and [the Court found] none, that either the CSA or 21 C.F.R. § 1306.04<sup>156</sup> fails to provide adequate notice of what conduct is prohibited."<sup>157</sup> The Court agreed with the U.S. Court for the East District of New York that "the government is obliged to prove, and the jury constrained to determine, what the medical profession would generally do in the

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<sup>153</sup> 21 U.S.C. § 841(a)(1) makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance [ . . . ]."

<sup>154</sup> 21 U.S.C. § 841(b) enumerates the penalties for violating § 841(a).

<sup>155</sup> Birbragher at 485.

<sup>156</sup> In the relevant part, 21 C.F.R. § 1306.04(a) states, "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. [ . . . ]"

<sup>157</sup> Birbragher at 488.

circumstances.”<sup>158</sup> In Birbragher’s case, the defendant did not give physical examinations (or ignored the results when he did), gave methadone outside of a clinic and without precautions against misuse, and did not regulate the dosage of the prescribed substances.<sup>159</sup> Upon these jury findings, it is unsurprising that the jury then concluded that Birbragher acted outside the usual course of professional practice and without a legitimate medical purpose.

The enactment of the RHA eliminates the government’s dependence on the jury to determine that a prescription without an in-person examination falls outside professional medical practice.

After all, Birbragher’s behavior was an egregious example of a physician acting as a “pusher.”<sup>160</sup>

Had Birbragher limited the dispensed doses and required clients to electronically sign a note promising that the drugs will only be used for legitimate purposes, the case would have been more difficult for the prosecution. The RHA allows prosecutors to use in-person examination as a sufficient indication of conduct that is outside the usual course of professional practice. The federal scope of the RHA also prevents website operators from moving to another state and continuing their illegal activity until the next state lawsuit.

### ***b. The registration requirement***

The RHA’s registration requirement is not entirely new to online pharmacies either. In its 2001 regulations, the DEA confirmed that an online pharmacy that sells controlled substances to the U.S. must register its physical location with the DEA.<sup>161</sup> Moreover, by 2008, when Congress passed the RHA, at least 40 state pharmacy boards licensed or registered all out-of-state

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<sup>158</sup> Id. at 489, quoting *United States v. Quinones*, 536 F.Supp.2d 267, 274 (E.D.N.Y.2008).

<sup>159</sup> Birbragher at 486.

<sup>160</sup> Id. at 486.

<sup>161</sup> Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 5.



pharmacies that provide services to residents in their respective states.<sup>162</sup> Building on the existing federal regulations, the RHA requires online pharmacies to obtain a special registration modification from the DEA to operate legally.<sup>163</sup> The RHA registration requirement arms the federal agencies with an efficient identification and prosecution tool for rogue online pharmacies: any online pharmacy that sells to U.S. customers without the explicit approval of the DEA violates the CSA. Because the RHA requires the display of contact information on each pharmacy's homepage, prosecutors can quickly ascertain whether a pharmacy is registered with the DEA.

### *c. Regulating intermediaries*

The RHA prohibits to “knowingly or intentionally [. . .] aid or abet” the delivery, distribution, or dispensing of controlled substances via the Internet.<sup>164</sup> The Act provides the following example as aiding under the RHA: “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 the dispensing of a controlled substance in [an unauthorized manner].”<sup>165</sup> The DEA's promulgated regulations note that the provision is “aimed squarely at the criminal facilitator whose ‘business plan’ for operating a rogue online pharmacy is to recruit an unscrupulous practitioner to write prescriptions...”<sup>166</sup>

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<sup>162</sup> Federation of States Medical Boards, Internet Prescribing Jurisdictions, updated April 2004, available at <http://www.fsmb.org/pdf/Agency%20Jurisdiction%20Chart--Internet.pdf>.

<sup>163</sup> RHA § 3(b), 21 U.S.C. § 823(f)

<sup>164</sup> RHA § 3(f), 21 U.S.C. § 841(h)(1).

<sup>165</sup> RHA § 3(f), 21 U.S.C. § 841(h)(2)(C).

<sup>166</sup> Drug Enforcement Administration, Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Final Rule, 74 Fed. Reg. 15596, 15604 (April 6, 2009).

However, the broad language of the provision would on its face apply to all Internet intermediaries. Therefore, the RHA tailors the provision by exempting (1) mere advocacy or pricing information without an offer to sell, (2) Internet access services<sup>167</sup> and Internet information location tools,<sup>168</sup> unless they “act in concert” with rogue pharmacy operators, and (3) mere indiscriminate and unfiltered handling of communication.<sup>169</sup>

These exceptions for Internet access services and information location tools (comprising the vast majority of Internet intermediaries, and possibly all of them), swallow the rule, all but requiring that the government show that an intermediary “acted in concert” with a rogue online pharmacy. In its regulation, the DEA proposes only one way to prove that a person “acted in concert” with the violator of the RHA – proving that the accomplice conspired to violate the RHA<sup>170</sup> or “aided and abetted such violation.”<sup>171</sup> The interwoven World Wide Web serves as a fertile ground for debate on the degree of “abetting” that intermediaries exercise when providing their services. Without further guidance or regulatory language, the government will have to prove with each type of intermediary that the intermediary “acted in concert” with the violator of the RHA.

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<sup>167</sup> As defined in 47 U.S.C. § 231(e): “a service that enables users to access content, information, electronic mail, or other services offered over the Internet, and may also include access to proprietary content, information, and other services as part of a package of services offered to consumers. Such term does not include telecommunications services.”

<sup>168</sup> As defined in 47 U.S.C. § 231(e): “a service that refers or links users to an online location on the World Wide Web. Such term includes directories, indices, references, pointers, and hypertext links.”

<sup>169</sup> RHA § 3(f), 21 U.S.C. § 841(h)(3).

<sup>170</sup> Specifically, 21 U.S.C. 841(h)(1).

<sup>171</sup> 74 Fed. Reg. 15596, 15605.

“Aiding and abetting” in the context of the CSA is a high bar for prosecution and conviction. A 2009 Tenth Circuit case, *United States v. Lovern*,<sup>172</sup> illustrates the application of the “aiding and abetting” standard in 21 U.S.C. § 841(h)(1)(B). In *Lovern*, the DEA prosecuted the operators of two rogue online pharmacies, based on their direct violation of the CSA.<sup>173</sup> The main issue for the Tenth Circuit concerned the sufficiency of evidence to convict two employees (a pharmacist and a computer technician) working for the website operators, on charges of conspiracy to violate the CSA as well as aiding and abetting under § 841(h)(1)(B).<sup>174</sup> The employees’ culpability hinged on whether they “knew the prescriptions they helped fill at [the rogue pharmacy] were issued by [third-party] physicians acting outside the usual course of professional medical practice or with a legitimate medical purpose.”<sup>175</sup>

The court first drew a distinction between the employees’ involvement and experience: the pharmacist, Lovern, possessed over 40 years of pharmacy experience and worked closely with the operators; whereas the computer technician, Barron, was a high school drop-out without any experience in the pharmaceutical industry, and without a similar level of involvement in the business.<sup>176</sup> In applying the standard to Barron, the court found that the following evidence fell short of the standard for conviction: (1) Barron sent a text message to a business affiliate stating, “[h]ook a brother up on scripts. I need some fake customers please. Mahahahaha;”<sup>177</sup> (2) Barron never registered with the state board of pharmacy, despite being told to do so by a state

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<sup>172</sup> 590 F.3d 1095 (10th Cir. 2009).

<sup>173</sup> *Lovern* at 1098-1099.

<sup>174</sup> *Id.* at 1099.

<sup>175</sup> *Id.* at 1104.

<sup>176</sup> *Id.* at 1098-1099.

<sup>177</sup> *Id.* at 1106-1007.

employee;<sup>178</sup> and (3) Barron sent an instant message to a business affiliate stating that a certain prescription for longer than 30 days was “very illegal,” but only after the pharmacy has been cited for issuing long-term drug amounts.<sup>179</sup> According to the court, the evidence sufficed for the inference that Barron knew that the pharmacy was unlawfully accepting prescriptions on the Internet,<sup>180</sup> but not that Barron knew that the contracted physicians issued prescriptions outside the usual course of professional practice or without a legitimate medical purpose.<sup>181</sup> Because a “general suspicion that an unlawful act may occur or that something criminal is happening is not enough” to convict a defendant under § 841(h)(1)(B), the court reversed Barron’s conviction.<sup>182</sup> *Lovern*’s standard for “aiding and abetting” under the CSA demonstrates the elements of proof that the DEA has to provide when prosecuting an intermediary under the RHA. At a minimum, the DEA has to show that the intermediary knows that the operator of an online pharmacy accepts business from the U.S., and knows either (1) that the pharmacy issues online prescriptions unlawfully, or (2) that the prescriptions are issued by doctors acting outside the usual course of medical practice. Because most Internet intermediaries provide neutral services (e.g. payment processing, publishing of content, domain registration), the nature of the business websites utilizing intermediaries is rarely documented or discussed in detail, leaving prosecutors no paper-trail to hold on to except when the prosecutors notify the intermediary. Moreover, screening rogue online pharmacies is challenging, as they are sometimes indistinguishable from legal online pharmacies. As a result, among Internet intermediaries, the intermediary exception

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<sup>178</sup> Id. at 1106.

<sup>179</sup> Id. at 1106.

<sup>180</sup> The government did not rely on this theory for prosecution.

<sup>181</sup> *Lovern* at 1106.

<sup>182</sup> Id. at 1107.

of the RHA is aimed at non-mainstream websites, which knowingly facilitate traffic toward rogue online pharmacies. One such example is the portal sites that serve to link search engine users to sale sites and Internet pharmacies.<sup>183</sup>

The RHA imposes a higher standard on one class of intermediaries—online advertisers of rogue pharmacies<sup>184</sup>—making it unlawful “to knowingly or intentionally use the Internet [. . .] to advertise the sale of [a controlled substance]” except as authorized by the CSA,<sup>185</sup> including placing an Internet advertisement “that directs prospective buyers to Internet sellers of controlled substances who are not registered with [an online pharmacy] modification [. . .].”<sup>186</sup> Unlike with the other intermediaries, the prosecution of online advertisers does not require proof that the online advertiser aided a rogue pharmacy, but merely that the advertiser knew about the rogue pharmacies’ use of its services.<sup>187</sup> The RHA also makes it unlawful to advertise websites whose activities violate the Controlled Substances Import and Export Act.<sup>188</sup> The prohibition covers websites that advertise the importation of controlled substances for “personal use.”<sup>189</sup> Although probably less demanding than the prosecution of intermediaries acting in concert with rogue pharmacy operators, the prosecution of advertisers requires evidence that the advertising websites put up the advertisements “knowingly or intentionally.” The DEA adopted the

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<sup>183</sup> See CASA *supra* note 3 for more background on portal sites and their role in promoting rogue Internet pharmacies.

<sup>184</sup> RHA § 3(g), 21 U.S.C. § 843(c)(2).

<sup>185</sup> RHA § 3(g)(2), 21 U.S.C. § 843(c)(2)(A).

<sup>186</sup> RHA § 3(g)(2), 21 U.S.C. § 843(c)(2)(B).

<sup>187</sup> RHA § 3(g), 21 U.S.C. 843(c)(2)(A); see also 74 Fed. Reg. 15596, 15605.

<sup>188</sup> 21 U.S.C. §§ 951-971.

<sup>189</sup> 74 Fed. Reg. 15596, 15605; 21 U.S.C. §§ 952, 957, 960(a)(1).

interpretation of the Eighth<sup>190</sup> and Fourth<sup>191</sup> Circuits in concluding that “a practitioner may be convicted of knowingly or intentionally dispensing controlled substances in violation of the CSA where the practitioner either (i) had actual knowledge of the illegal activity or (ii) was presented with facts that put him on notice that criminal activity was particularly likely and yet intentionally failed to investigate those facts.”<sup>192</sup> A similar standard applies to pharmacists,<sup>193</sup> and thus probably online advertisers. Whatever the exact scope, the problem of proof can be resolved by the DEA by notifying the advertiser that one or more of its business clients violate the CSA.

There are several reasons to impose a higher duty of care on online.<sup>194</sup> Online advertising services are effective at channeling traffic to rogue pharmacies; advertisers profit from the advertising activity; and advertisers have an established poor record in filtering out rogue pharmacies both from search results and from submitted ads.<sup>195</sup> While prosecutors relied on the FDCA in the recent investigation of Google’s AdWords practices, the RHA’s advertiser provision is a viable option as well for similar prosecutions. The RHA allows criminal prosecution, as does the FDCA, and even sets a lower proof standard. There are three possible explanations regarding the preference of the DOJ to build the investigation on the FDCA

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<sup>190</sup> *United States v. Katz*, 445 F.3d 1023, 1031 (8th Cir. 2006), cert. denied, 127 S.Ct. 421 (2006).

<sup>191</sup> *United States v. Lawson*, 682 F.2d 480, 482 (4th Cir. 1982) (citations omitted), cert. denied, 459 U.S. 991 (1982).

<sup>192</sup> 74 Fed. Reg. 15596, 15605.

<sup>193</sup> *Id.* at 15606.

<sup>194</sup> For an argument in favor of regulating Internet advertisers see Bryan Liang, *Searching For Safety: Addressing Search Engine, Website, And Provider Accountability For Illicit Online Drug Sales*, 35 *Am. J.L. & Med.* 125 (2009).

<sup>195</sup> See discussion *supra* in part III(b)(ii).

provisions: first, it is likely that the investigation of Google began before the passage of the RHA;<sup>196</sup> second, the prosecutors may have intended to capture ads from online pharmacies that sell prescription drugs not classified as controlled substances; and third, on the federal side, the investigation was conducted by the FDA's Office of Criminal Investigations, and not the DEA. In sum, the RHA allows the DEA to prosecute websites that focus on illegal activity, but not the mainstream intermediaries that serve as traffic highways online.

#### *d. Effects of the RHA*

According to some DEA officials, the RHA has eliminated U.S.-based rogue online pharmacies.<sup>197</sup> (About 50% of online pharmacies are hosted in the U.S.,<sup>198</sup> and only 24% of the drugs sold online are shipped from the U.S..<sup>199</sup>) It appears that the DEA has accordingly reduced the resources devoted to the problem, relying on the deterring effect of the new legislation.<sup>200</sup> Indeed, in an October 2010 conference, the DEA's pharmaceutical investigation chief has

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<sup>196</sup> Google found out about the investigation in 2009, so it is plausible that the investigation began before October 2008, when the RHA passed. See Department of Justice, Google Forfeits \$500 Million Generated by Online Ads & Prescription Drug Sales by Canadian Online Pharmacies, Press Release, August 24, 2011, at <http://www.justice.gov/opa/pr/2011/August/11-dag-1078.html>.

<sup>197</sup> See e.g. Susan Schulman, *Feds crack down on online prescribing*, Buffalo News, March 22, 2011, available at <http://www.buffalonews.com/city/special-reports/rx-for-danger/article373746.ece> (statement of DEA Supervisory Special Agent Gary Boggs).

<sup>198</sup> OpSec Security, *supra* note 13.

<sup>199</sup> CASA, *supra* note 3.

<sup>200</sup> DEA filed a mere handful of cases based on the RHA since the law took effect.

downplayed the problem as manageable in the aftermath of the RHA.<sup>201</sup> Outside the DEA's statements, there is little published evidence that the RHA succeeded in curbing the growth of rogue online pharmacies. Moreover, the studies that analyzed the post-RHA Internet pharmacy industry did not confirm DEA's optimism.<sup>202</sup> The best indicator of the total effect would be gauging the volume of illegal controlled substance sales via the Internet. Since measuring the volume of black markets is difficult, researchers can also approximate the effect by analyzing the changes in availability of drugs from online pharmacies and the DEA's success in enforcing the RHA to shut down websites.

A 2009 study assessed the online availability of seventeen popular drugs between 2007 and 2009, and found that "a growing number of online pharmacies have abandoned the basic requirement of a valid prescription."<sup>203</sup> During the two years of the study, the number of online pharmacies that do not require a prescription or only require an online consultation grew by 65%.<sup>204</sup> Alarming, the study showed that the counterfeit drug pipeline does not show signs of drying up: the study revealed a 30% increase in the number of listings offering bulk pharmaceuticals and active ingredients across multiple popular business-to-business trade boards.<sup>205</sup> The results indicate that even if fewer rogue Internet pharmacies operate from the U.S., the supply and availability of counterfeit drugs remains.

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<sup>201</sup> Robert Hill, Chief of the DEA's pharmaceutical investigations section, Partnership for Safe Medicines conference on counterfeit drugs, October, 2010, <http://www.c-spanvideo.org/program/DrugProf>.

<sup>202</sup> This can be in part because the studies were conducted by watchdog organizations.

<sup>203</sup> OpSec Security, *supra* note 13.

<sup>204</sup> *Id.*

<sup>205</sup> *Id.*



Another study, conducted by an online pharmacy watchdog organization LegitScript, looked at the DEA's efforts to enforce the RHA.<sup>206</sup> The researchers in the study listed a 1,000 rogue Internet pharmacies, more than half of which are located in the U.S. to demonstrate that the RHA did not eliminate the problem of illegal online sales of controlled substances. The study investigates several rogue pharmacies' registration information, revealing that a large number of them are almost certainly run from the U.S.<sup>207</sup> The researchers argue that the DEA should take action against rogue pharmacies that depend entirely on U.S. domain name registrars, servers, and delivery services. The study also uncovers some of the techniques used by rogue pharmacy operators to avoid prosecution, such as creating several versions of the website that alternate based on the link that brings the user to the rogue pharmacy. The researchers conclude that the DEA has far from accomplished its mission to minimize the illegal sales of controlled substances online.<sup>208</sup>

The contrast between the studies and the DEA's views highlights the need for additional research on the online market for pharmaceuticals. Additionally, the DEA's views may simply reflect the agency's priorities rather than a perceived success in blocking illicit online drug sales.

#### ***e. Where the RHA falls short***

The RHA provides new authority for the DEA, but also falls short in at least two areas: foreign Internet pharmacies and prescription drugs not classified as controlled substances.

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<sup>206</sup> Legit Script, Drug Dealers on the Internet: Is the DEA enforcing the Ryan Haight Act?, June 2011, <http://www.legitscript.com/download/LegitScript-DEA-Rogue-Internet-Pharmacy-Analysis.pdf>.

<sup>207</sup> Id.

<sup>208</sup> Id.

### **i. Foreign Internet pharmacies**

The RHA allows the DEA to target domestic questionnaire pharmacies more effectively, but there is little in the RHA's language to address 'pill mills' abroad, which comprise about 50% of all rogue online pharmacies. In the age of global e-commerce, enforcement alone cannot stop the proliferation of foreign rogue online pharmacies.<sup>209</sup> Even with perfect cooperation from other countries, the online sale of the prescription drugs often occurs in nations that do not prohibit such sales themselves. As a result, while the DEA celebrates the success of the RHA, the new Act is limited to only half the black market at the outset.

When the U.S. Senate Committee on the Judiciary solicited advice on regulating online pharmacies, the global character of the problem was raised by Professor Philip Heymann, who suggested a regulation scheme to reach both questionnaire pharmacies domestically and anonymous "pill mills" around the globe by imposing new requirements on Internet search engines and payment intermediaries.<sup>210</sup> Professor Heymann's testimony was based on his work with "Keep Internet Neighborhoods Safe" (KINS), a collaboration of the Center for International Criminal Justice at Harvard Law School, Drug Strategies, the Treatment Research Institute at the University of Pennsylvania, and the Weill Medical Center at Cornell University. The group held several meetings and a major conference to discuss the regulatory options in protecting youth

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<sup>209</sup> For a detailed explanation, 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 (2006); see also Bryan Liang, *Searching For Safety: Addressing Search Engine, Website, And Provider Accountability For Illicit Online Drug Sales*, 35 AM. J.L. & MED. 125 (2009).

<sup>210</sup> *Rogue Online Pharmacies: the Growing Problem of Internet Drug Trafficking: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Philip Heymann, James Barr Ames Professor of Law, Harvard Law School, former U.S. Deputy Att'y Gen. of the United States).

from the availability of addictive drugs online. KINS meetings participants included representatives of all the major stakeholders and government offices: internet service providers, search engines, banks, credit card companies, private carriers, the National Institute of Drug Abuse, DOJ, DEA, the Department of State, and staff members from key Senate and House Committees.

In his testimony, Professor Heymann reintroduced KINS's key published recommendations, urging the Committee to complement the direct regulation of rogue websites with the regulation of Internet intermediaries. The logic of this argument is firm: e-commerce websites depend on the cooperation of search engines to be found, payment intermediaries to be paid online, shipping couriers to deliver their products, Internet service providers to be accessed, and domain name registrants to own a website name. Specifically, under KINS's recommendations, (1) ISPs should offer a "parental control" filtering service for customers, (2) payment intermediaries must test, and if necessary, shut down, any merchants that are reported as illegal by DOJ, and (3) search engines should display a prominent banner "that reminds the requestor that it is illegal to buy or sell this drug in the United States without a prescription" whenever a user enters certain terms.<sup>211</sup> To update the Internet intermediaries' databases of alleged offenders and related search terms, KINS recommended the creation of an independent monitoring group, a small non-profit comprising "a group of individuals simply using search engines to identify websites offering to sell controlled substances without valid prescriptions." The independent monitoring group would combine the investigative information that is currently dispersed among the agencies.

Despite the potential effectiveness of KINS's recommendations, the Committee rejected the broader regulatory approach because "[w]hile leading credit card companies and Internet service

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<sup>211</sup> Id.

providers did express general support for many of the plenary group's ideas, their preference was for encouraging voluntary compliance rather than legislative or regulatory mandates.”<sup>212</sup> The Committee curtailed the RHA's intermediary liability provisions to the “aid and abet” standard discussed *supra*, allowing the major intermediaries to self-regulate.

## **ii. Prescription drugs not classified as controlled substances**

Another notable limitation of the RHA is that the Act addresses only the sales of controlled substances rather than the sales of all prescription medicine. According to the DEA, “[a] controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence.”<sup>213</sup> The “safest” controlled substances, those classified as Schedule IV or V, have some potential for abuse.<sup>214</sup> On the other hand, the need for a prescription is determined by the FDA when the agency evaluates a drug's safety.<sup>215</sup> By limiting the RHA to controlled substances, the authors of the RHA ignored the risk of self-medicating with prescription drugs not classified as controlled substances.

In 21 U.S.C. § 353(b)(1), the FDCA enumerates two situations in which a drug may be limited to a prescription-only status: (A) a drug which “because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe

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<sup>212</sup> Ryan Haight Online Pharmacy Consumer Protection Act of 2007, Report of the U.S. Senate Committee on the Judiciary, September 17, 2008. Rep. 110-521, 110th Congress, 2d Session.

<sup>213</sup> Drug Enforcement Agency, Office of Diversion, Controlled Substance Schedules, November 2011, [www.deadiversion.usdoj.gov/schedules/index.html](http://www.deadiversion.usdoj.gov/schedules/index.html).

<sup>214</sup> *Id.*

<sup>215</sup> 21 U.S.C. § 353(b)(1); 21 U.S.C. § 355. The authority of the agency to determine the prescription status of a drug was affirmed in *Nat'l Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688 (2d Cir. 1975).

for use except [by prescription];”<sup>216</sup> and (B) a drug which is limited to prescription status in the new drug approval process.<sup>217</sup> The FDA relies on 21 U.S.C. § 353(b)(1)(B) to limit virtually all new chemical entity drugs to prescription-only status. Drug manufacturers may apply for an over-the-counter (OTC) status after at least five years of marketing, during which the agency evaluates the safety of the drug and the potential effects of self-medication.<sup>218</sup>

The second situation, described in § 353(b)(1)(A), consists of three factors: toxicity, potentiality for harmful effect, and the method of use or collateral measures necessary to use. Toxicity encompasses the risk posed by incorrectly titrating the drug, but does not extend to all misuse.<sup>219</sup> Other potentiality for harmful effect refers to a broader set of considerations related to ingesting the drug, including potential for abuse and the potential for tampering.<sup>220</sup> Finally, the last factor, methods of use and collateral measures necessary, encompasses the risks of all possible circumstances under which a drug is used, including policy and enforcement considerations.<sup>221</sup>

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<sup>216</sup> 21 U.S.C. § 353(b)(1)(A).

<sup>217</sup> 21 U.S.C. § 353(b)(1)(B).

<sup>218</sup> See Peter B. Hutt, Richard A. Merrill, Lewis A. Grossman, *Food and Drug Law: Cases and Materials*, Ch. 4(i) (3rd ed. 2007).

<sup>219</sup> See *United States v. Article of Drug Labeled "-Decholin-*", 264 F. Supp. 473 (E.D. Mich. 1967).

<sup>220</sup> See Peter B. Hutt, “A Legal Framework for future Decisions on Transferring Drugs from Prescription to Nonprescription Status,” *Food Drug Cosmetic Law Journal* 37, No. 427 (1982).

<sup>221</sup> For an example of a broad interpretation see *United States v. General Nutrition, Inc.*, 638 F. Supp. 556 (W.D.N.Y. 1986) (Accepts the FDA’s reasoning that mega-doses of vitamins A and D should require prescription because of the wide public misperception that vitamin mega-doses are effective in treating various diseases.)

Although the FDA's prescription status determination was seriously questioned in an early case,<sup>222</sup> the last case on the question indicated a deferral to the FDA's judgment.<sup>223</sup>

A Kansas case demonstrates how the illegal online sale of prescription drugs not classified as controlled substances presents a less favorable prosecution fact-pattern. In *State ex rel. Stovall v. ConfiMed.com, L.L.C.*,<sup>224</sup> the Kansas Attorney General sued a physician that issued online prescriptions for Kansas residents through an online out-of-state pharmacy. The court concluded that the physician did not violate Kansas' consumer protection law<sup>225</sup> when he failed to perform a physical examination and sold Viagra, a prescription drug, to a minor. Notably, the trial court highlighted that "there was no actual harm done to anyone[,] [n]othing was misrepresented[, and a]ll drugs furnished were authentic."<sup>226</sup> These factors are significant in evaluating the violation of a consumer protection law, leading the court to the correct decision. Indeed, in the states that have not yet banned online prescription, neither state nor federal regulators have authority to discipline a physician working with a rogue online pharmacy, unless the pharmacy misrepresents its products, imports drugs from abroad, or sells adulterated or misbranded drugs.

It is possible to reconcile the RHA's limitation to controlled substances with the FDA's finding that many drugs not classified as controlled substances are unsafe for self-medication. As often

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<sup>222</sup> *United States v. Article of Drug Labeled "-Decholin-"*, 264 F. Supp. 473 (E.D. Mich. 1967) (The court evaluated the FDA's evidence on the questions of toxicity and collateral measures, dismissing the case with prejudice to the FDA.)

<sup>223</sup> *United States v. General Nutrition, Inc.*, 638 F. Supp. 556 (W.D.N.Y. 1986) (Applies a deferential "arbitrary or capricious" review to the FDA's decision to require prescription for mega-doses of vitamins.)

<sup>224</sup> 38 P.3d 707 (2002).

<sup>225</sup> The Kansas Consumer Protection Act makes "unconscionable" conduct unlawful.

<sup>226</sup> *ConfiMed* at 710.

is the case with major laws regulating food and drug, the passage of the RHA was carried on a wave of visible problem, namely, the death of a young man who purchased oxycotin online.<sup>227</sup> The call for action was amplified by the reports of increased pharmaceutical drug abuse,<sup>228</sup> without a similar amplification for drugs not classified as controlled substances.<sup>229</sup> The resulting legislation is best viewed as a reflection of priorities in a reactionary legislative environment. Although legislators have proposed bills creating RHA-style requirements for drugs not classified as controlled substances,<sup>230</sup> the efforts are unlikely to succeed without the same catalyst and movement that carried the RHA through the legislation process. As discussed *infra*, since the passage of the RHA Congress has considered legislation to expand the regulation to both foreign-based websites and to prescription drugs not classified as controlled substances.

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<sup>227</sup> For more background see Reaching Youth Abusing Narcotics at [http://www. Ryanscause.org](http://www.Ryanscause.org).

<sup>228</sup> Ryan Haight Online Pharmacy Consumer Protection Act of 2007, Report of the U.S. Senate Committee on the Judiciary, September 17, 2008. Rep. 110-521, 110th Congress, 2d Session.

<sup>229</sup> The FDA's earlier testimony on Internet drug sales cited high violation rates, but could not match the DEA in citing confirmed adverse effects. See Internet Drug Sales: Hearings before the H.R. Committee on Government Reform, 104th Congress. (2004) (Statement of William K. Hubbard, Associate FDA Commissioner for Policy and Planning)

<sup>230</sup> See e.g. Online Pharmacy Safety Act of 2011, Senate Bill S. 2002, 112th Congress (2011). Text available at <http://www.opencongress.org/bill/112-s2002/text>.

## 5) RECENTLY PROPOSED LEGISLATION

### *a. Legislation aimed at counterfeit drugs*

Two years after the passage of the RHA, Committee Chairman Leahy introduced legislation to regulate Internet intermediaries, this time as a means to shut down websites that share copyrighted materials illegally. The bill, titled Combating Online Infringement and Counterfeits Act (“COICA”), would authorize the U.S. Attorney General to commence an action in rem against a domain name used by an Internet site that is “dedicated to infringing activities,” even if the domain name is located outside of the U.S.<sup>231</sup> Following the commencement of an action, the court would be authorized to serve any ISPs, financial transaction providers, and Internet advertising services to take “technically feasible” or other specified reasonable measures to prevent infringing activities from continuing. The COICA’s definition of an Internet site “dedicated to infringing activities” included any website, domestic or foreign, that is “primarily designed [...] to sell or offer to sell or distribute or otherwise promote goods, services, or materials bearing a counterfeit mark [...], and [...] such activities are the central activities of the Internet site.”<sup>232</sup> Both domestic and foreign online pharmacies that sell counterfeit medicine would fall under the definition. The COICA also would grant immunity to Internet intermediaries acting pursuant to a court order, as well as to Internet intermediaries voluntarily declining service to domain names that the intermediaries believe are dedicated to infringing activities.<sup>233</sup> To mitigate the broad approach of the bill, the COICA would require the court to

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<sup>231</sup> Combating Online Infringement and Counterfeits Act, Senate Bill S.3804, 111th Congress (2010).

<sup>232</sup> *Id.*, § 2(a)(1).

<sup>233</sup> *Id.*, § 2(e)(5).



ensure that a foreign website alleged to be “dedicated to infringing activities” has sufficient ties to the U.S.<sup>234</sup>

The COICA generated wide opposition from the Internet community, privacy advocates, and technology companies. Dozens of law professors from all over the world expressed their objections to the bill in a formal letter to the Committee.<sup>235</sup> The group asserted that the bill (1) abridged freedom of speech by allowing to shut down websites without an opportunity to object, (2) suppressed protected speech containing no infringing content by requiring the closure of subdomains, and (3) introduces censorship. In the end, what fifty one law professors could not achieve with a legal argument, one senator accomplished using the arcane<sup>236</sup> Senate rules. After passing through the Committee on the Judiciary with flying colors, the COICA was put “on hold” and thus killed by Senator Wyden, on the belief that the “COICA’s at-all-costs approach to protecting intellectual property would have inflicted collateral damage on the foundations of the

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<sup>234</sup> COICA would allow to bring action against foreign domains if (1) such a domain is used within the United States to access an infringing site; (2) the site directs business to U.S. residents; and (3) the site harms U.S. intellectual property rights holders. (§ 2(d)(2)(A)). In determining whether a site directs business to U.S. residents, COICA would require the court to consider the following: (1) whether goods or services are being provided to U.S. users; (2) intent; (3) prevention measures; and (4) whether any prices for such goods and services are indicated in U.S. currency. (§ 2(d)(2)(B))

<sup>235</sup> Law Professors’ Letter in Opposition to S. 3804, November 16, 2010, available at [www.publicknowledge.org/files/docs/LawProfCOICA.pdf](http://www.publicknowledge.org/files/docs/LawProfCOICA.pdf).

<sup>236</sup> See e.g. The New Yorker, The Empty Chamber, August 9, 2010, available at [http://www.newyorker.com/reporting/2010/08/09/100809fa\\_fact\\_packer](http://www.newyorker.com/reporting/2010/08/09/100809fa_fact_packer).

Internet, trampled free speech, stifled innovation and given license to foreign regimes to further censor the Internet for political and commercial purposes.”<sup>237</sup>

The COICA was resurrected in a revised form in May 2011, when Senator Leahy introduced the “Preventing Real Online Threats to Economic Creativity and Theft of Intellectual Property Act of 2011” (PIPA).<sup>238, 239</sup> The new legislation shifted focus to nondomestic domain names only, and added online search engines (covered by the term “information location tool”) to the list of affected Internet intermediaries. In its most relevant part, the PIPA introduces a new section to address rogue pharmacies that do not require a valid prescription when selling prescription drugs.<sup>240</sup> The section is less burdensome on Internet intermediaries, addressing only their voluntary actions. Specifically, it provides immunity from liability to any Internet intermediary<sup>241</sup> that stops providing services to a site that it believes “endangers the public health.”<sup>242</sup> Under the Act, an ‘infringing Internet site that endangers the public health’ includes “an Internet site that is [...] operated [...] primarily as a means for offering, selling, dispensing,

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<sup>237</sup> Press Release, U.S. Senator Ron Wyden, Senator Wyden Response to the PROTECT IP Act Introduction (May 12, 2011).

<sup>238</sup> Preventing Real Online Threats to Economic Creativity and Theft of Intellectual Property Act of 2011, Senate Bill S. 968, 112th Congress (2011).

<sup>239</sup> The companion bill in the U.S. House of Representatives is the Stop Online Piracy Act, H. R. 3261, 112th Congress (2011).

<sup>240</sup> Id. § 5(b).

<sup>241</sup> Internet intermediaries include registry, registrar, financial transaction provider, information location tool, or Internet advertising service.

<sup>242</sup> PIPA § 5(b)(2).

or distributing any controlled or non-controlled prescription medication, and does so regularly without a valid prescription[,] or [...] for medication that is adulterated or misbranded.”<sup>243</sup>

The PIPA thus creates two new regulatory approaches to regulating rogue online pharmacies based abroad. First, if the U.S. Attorney General determines that a foreign site is dedicated to selling counterfeit drugs, she may commence a legal action, and the court may order Internet intermediaries to deny service to the rogue pharmacy. Second, if an Internet intermediary denies service to a website it considers a rogue online pharmacy, the intermediary is immune from a lawsuit. The immunity is granted regardless of the location of the domain name (domestic or abroad), the authenticity of the drugs (counterfeit or not), and the website’s market (whether the pharmacy deals with U.S. residents or not). Therefore, what the immunity provisions hold back in regulatory requirements, they make up for in the breadth of their reach. Presumably, Congress would not so arm the private entities that service rogue pharmacies unless it expected them to use the newly granted powers. By protecting the Internet intermediaries in dealing with rogue online pharmacies, the legislation inadvertently applies pressure on the intermediaries to cooperate with the agencies seeking to shut down such pharmacies.

### **i. Intermediary provisions and their potential effects**

The PIPA incorporated elements of Professor Heymann’s advice, with separate regulatory provisions for different types of Internet intermediaries. Each of the provisions is likely to have both positive and negative consequences.

The PIPA requires financial transaction providers to “take reasonable measures, as expeditiously as reasonable, designed to prevent, prohibit, or suspend its service from completing payment

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<sup>243</sup> Id. § 5(b)(3)(B)(ii).

transactions involving customers located within the United States and the Internet site.”<sup>244</sup> As policymakers learned from regulating online gambling, the regulation of payment intermediaries can be effective against infringing websites, but is also prone to adverse consequences.

Specifically, the void left by the major payment processors may be filled by off-shore payment intermediaries, specializing in avoiding U.S. law.<sup>245, 246</sup> The trend was evident in the passage of the RHA as well, which was marked by an increase in online pharmacies that do not require a prescription compared to online pharmacies that do.<sup>247</sup>

The PIPA also mandates the operators of non-authoritative domain name servers (“DNS”)<sup>248</sup> to “take the least burdensome technically feasible and reasonable measures designed to prevent the

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<sup>244</sup> PIPA § 3(d)(2)(B).

<sup>245</sup> For a discussion on the payment intermediary cottage industry following the passage of the Unlawful Internet Gambling Act of 2006, see Ian Abovitz, *Why the United States Should Rethink Its Legal Approach to Internet Gambling: A Comparative Analysis of Regulatory Models That Have Been Successfully Implemented in Foreign Jurisdictions*, 22 *Temp. Int'l & Comp. L.J.* 437 (2008).

<sup>246</sup> See e.g. <http://www.offshorepaymentprocessing.com/FAQ.html> (listing the following as ‘high risk merchants’ that would benefit from offshore payment processing: adult service providers, pharmaceutical merchants, terminated merchant file accounts. See also <http://www.intabill.com/> (advertising for pharmaceuticals and gambling websites on the front page.)

<sup>247</sup> OpSec Security, *supra* note 13.

<sup>248</sup> Crocker et al. explain the technical parts of the Act: “The domain-name system, or DNS, is a system that makes the Internet more accessible to humans. When computers on the Internet communicate with each other, they use a series of numbers called “IP addresses” (such as 156.33.195.33) to direct their messages to the correct recipient. These numbers, however, are hard to remember, so the DNS system allows humans to use easier-to-remember words (such as “senate.gov”) to access websites or send e-mail. Such names resolve to the proper IP numbers through the use of domain name servers. These servers are set up in a distributed fashion, often globally, such that resolution of names connected to IP addresses may pass through many servers during Internet data flow. To make

domain name described in the order from resolving to that domain name's Internet protocol address." These "reasonable measures" do not include the modification of the DNS operator's network, software, system, or facilities.<sup>249</sup> The function of each of the ten million non-authoritative DNS servers is to direct users who enter domain names, such as

'www.accessrx.com,' to the websites' respective IP addresses, such as '173.223.22.116.'<sup>250</sup>

Unlike authoritative DNS operators, which provide the information based on their records, non-authoritative DNS operators redirect users based on a cache file that contains the results of previous contacts with authoritative servers.<sup>251</sup> Under a PIPA court order, a non-authoritative DNS server operator would have to redirect the user to a textual notice instead of the correct IP address. The website will remain at its IP address, but the user would not be able to reach the website by entering the familiar domain name.

Although the U.S. has never filtered DNS traffic, the experience of China and other countries has shown several dangerous drawbacks to DNS filtering. Besides standing in tension with existing Internet security measures, DNS filtering may easily be circumvented using user-friendly tools.

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the DNS faster and less expensive to operate, over ten million so-called "recursive servers" exist as accelerators of convenience, to store and retransmit DNS data to nearby users. PIPA proposes legal remedies for infringement that would affect the operators of these "recursive servers," which are the type of DNS servers used by the computers of end users to resolve DNS names in order to access content on the Internet." Steve Crocker, David Dagon, Dan Kaminsky, Danny McPherson, and Paul Vixie, Security and Other Technical Concerns Raised by the DNS Filtering Requirements in the PROTECT IP Bill, May 2011, at <http://s3.amazonaws.com/dmk/PROTECT-IP-Technical-Whitepaper-Final.pdf>.

<sup>249</sup> PIPA § 3(d)(2)(A).

<sup>250</sup> This is an example of a real-life questionnaire pharmacy.

<sup>251</sup> The Office of Enterprise Technology, the State of Minnesota. DNS Authority, last updated 3/22/2011, available at <http://www.mnet.state.mn.us/data-net/dns/authority.php#dnsnonauth>.

Once circumvented the policy may compromise Internet safety. Worse yet, the website itself may change the DNS settings on the user's computer with or without the user's knowledge. Once the user's settings are changed to contact a foreign DNS server to look up IPs, it becomes prone to misdirection when trying to access other websites as well.<sup>252</sup>

PIPA further requires Internet advertising services, upon a court order, to "take technically feasible and reasonable measures, as expeditiously as reasonable," to prevent its service from providing advertisements to the website, and to cease making available advertisements, links, or any other access points to the domain name."<sup>253</sup> In addition to the advertising services' current duty to act when notified of advertising by rogue pharmacies,<sup>254</sup> the Act requires the advertising services to deny service to alleged counterfeit-drugs pharmacies upon a court order. For counterfeit-drug pharmacies, the change in the law is minor. Advertising services "use the Internet" to "advertise the [unauthorized] sale of [...] controlled substances."<sup>255</sup> Knowledge of illegal activity by their customers is the only remaining legal factor to hold the advertising networks criminally liable under CSA.<sup>256</sup> Currently, DOJ may rely on academic articles and

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<sup>252</sup> For a full argument on the adverse consequence of filtering DNS traffic, see Steve Crocker, David Dagon, Dan Kaminsky, Danny McPherson, and Paul Vixie, Security and Other Technical Concerns Raised by the DNS Filtering Requirements in the PROTECT IP Bill, May 2011, at <http://s3.amazonaws.com/dmk/PROTECT-IP-Technical-Whitepaper-Final.pdf>.

<sup>253</sup> PIPA § 3(d)(2)(C).

<sup>254</sup> Ryan Haight Act, § 3(g) (21 U.S.C. 843(c)(2)(A)).

<sup>255</sup> *Id.*

<sup>256</sup> *Id.*

reports to establish the advertising service's knowledge of the activity;<sup>257</sup> whereas under PIPA, the court order serves to establish that knowledge.

The proposed requirement for advertising systems is feasible, and would not cause adverse consequences. Combined, the RHA and the PIPA would require advertising services both to maintain reasonable safeguards to prevent advertising of rogue pharmacies and to remove any advertising by counterfeit-drug pharmacies when served by a U.S. court. Modern advertising services, such as Google's AdWords and Microsoft's adCenter, are experts at collecting and analyzing information on the Internet, and will be able to comply with court orders under both Acts. Moreover, for the major advertisers, compliance would require no more than a stricter adherence to the advertising services' own policies. Without the regulation, advertising services have incentive to profit at the expense of their customers' safety, which may be the reason the advertising services have been slow to comply. There is no third-party offshore alternative when it comes to advertising on the popular advertising networks, although rogue pharmacies may continue to advertise on websites of lower reputation. Once rogue pharmacies have only temporary access to the major advertising services before having their ads removed, the pharmacies are likely to intensify their focus on the other main method of attracting new Internet customers: search engine optimization.<sup>258</sup>

To prevent search-generated traffic to counterfeit-drugs pharmacies for confused and aware users alike, the PIPA requires search engines to "take technically feasible and reasonable measures, as expeditiously as possible, to remove or disable access to Internet site [...] or not serve a

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<sup>257</sup> <sup>257</sup> The Wall Street Journal, Google Was Warned on Rogue Drug Ads, May 21, 2011, available at <http://online.wsj.com/article/SB10001424052748704083904576335483063623402.html>.

<sup>258</sup> Due to their ephemeral nature, rogue online pharmacies depend on constant inflow of new customers. CASA, *supra* note 3.

hypertext link to such Internet site.”<sup>259</sup> Upon a court order, search engines would be required to manually remove certain listings from their databases, probably without an explanation to the search engine user. Google has manipulated its search before to accommodate the Chinese government by eliminating search results for certain keywords,<sup>260</sup> but this policy would require the removal of the domain name from the search results globally.

Many Internet commentators, including Google’s Chairman, find the manipulation of search results a dangerous precedent to free speech online.<sup>261</sup> Moreover, search engine rankings have been granted First Amendment protection against a claim of tortious interference with contract in *Search King Inc. v. Google Technology, Inc.*<sup>262</sup> In *Search King*, a U.S. District judge found Google’s website rankings to be an opinion because its results are Google’s subjective view of the relevance of websites to the query, even if the algorithm itself is objective and automated. However, as the influence of Internet intermediaries continued to grow, several commentators presented cases against a laissez faire regulatory approach to page rankings.<sup>263</sup> Since the U.S. is

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<sup>259</sup> PIPA § 3(d)(2)(D).

<sup>260</sup> Breitbart, Google Agrees to Censor Results in China, January 24, 2006, <http://www.breitbart.com/news/2006/01/24/D8FBCF686.html>.

<sup>261</sup> The Guardian, Google boss: anti-piracy laws would be disaster for free speech, May 18, 2011, available at <http://www.guardian.co.uk/technology/2011/may/18/google-eric-schmidt-piracy>.

<sup>262</sup> 2003 WL 21464568 (W.D. Okla. 2003) (applying Oklahoma law).

<sup>263</sup> See Frank Pasquale, Beyond Innovation and Competition: The Need for Qualified Transparency in Internet Intermediaries, 104 NW. U. L. R. 105, 106 (2010) (advocating the creation of Internet Intermediary Regulatory Council to regulate search engines and ISPs); Frank Pasquale, Rankings, Reductionism, and Responsibility, 54 CLEV. ST. L. REV. 115, 139 (2006) (arguing that the effects of search engines’ free speech should be weighed in determining how much protection is due); Liang and Mackey supra, note 93 (arguing that search engines do not have sufficient incentive to protect their users).



yet to regulate Internet search results, it is difficult to predict the outcome of the search engine intermediary provision.

## **ii. The PIPA's fate**

The PIPA was introduced with an auspicious bipartisan support. When the Senate Judiciary Committee held hearings on the legislation, twelve of the seventeen Committee members, appeared as co-sponsors of the bill, ultimately granting the legislation unanimous approval.<sup>264</sup> By November 2011, in preparations for the Senate floor vote, the PIPA enjoyed an enviable sponsor list of 40 Senators from both political parties. The Recording Industry Association of America (RIAA) did not shy away from taking credit for goading much of the political support.<sup>265</sup> But the closer the PIPA moved to passing, the more controversy the Act generated in the Internet community.<sup>266</sup> By January, the PIPA generated a firestorm on the Internet, which

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<sup>264</sup> U.S. Senate Judiciary Committee, Opening Statement of Sen. Patrick Leahy, Committee Chair, May 26, 2011, available at

[http://www.judiciary.senate.gov/hearings/testimony.cfm?id=e655f9e2809e5476862f735da16d92d1&wit\\_id=e655f9e2809e5476862f735da16d92d1-0-0](http://www.judiciary.senate.gov/hearings/testimony.cfm?id=e655f9e2809e5476862f735da16d92d1&wit_id=e655f9e2809e5476862f735da16d92d1-0-0).

<sup>265</sup> See RIAA Press Release, Analysis: Rogue Sites Bill Enjoys Rare, Extensive Bipartisan Support, November 2011, at

[http://riaa.com/newsitem.php?content\\_selector=newsandviews&news\\_month\\_filter=11&news\\_year\\_filter=2011&id=B74C7B2B-68EC-EBE9-6CB9-946F517749B1](http://riaa.com/newsitem.php?content_selector=newsandviews&news_month_filter=11&news_year_filter=2011&id=B74C7B2B-68EC-EBE9-6CB9-946F517749B1).

<sup>266</sup> See e.g. Jon Healy, Technology Entrepreneurs blast the Protect IP Act, Los Angeles Times, September 8, 2011, available at <http://opinion.latimes.com/opinionla/2011/09/technology-entrepreneurs-blast-the-protect-ip-act.html>.

This is a small sample of hundreds of online articles opposing the PIPA.

eventually killed the support for the bill overnight.<sup>267</sup> The specific night was January 18, 2012, when major websites, such as Wikipedia and Reddit, “blackout” for 24 hours in protest.<sup>268</sup>

The Internet community’s opposition to the PIPA is best summarized by Wikipedia:

SOPA and PIPA would put the burden on website owners to police user-contributed material and call for the unnecessary blocking of entire sites. Small sites won't have sufficient resources to defend themselves. Big media companies may seek to cut off funding sources for their foreign competitors, even if copyright isn't being infringed. Some foreign sites would be prevented from showing up in major search engines. And, SOPA and PIPA build a framework for future restrictions and suppression.<sup>269</sup>

Since then, even Chris Dodd, the main lobbyist for the RIAA, admitted that the PIPA is “dead.”<sup>270</sup> But the PIPA’s death did not halt Congress’s efforts to regulate Internet intermediaries to combat rogue online pharmacies.

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<sup>267</sup> See Jenna Wortham, With Twitter, Blackouts and Demonstrations, Web Flexes Its Muscle, New York Times, January 18, 2012, available at [http://www.nytimes.com/2012/01/19/technology/protests-of-antipiracy-bills-unite-web.html?\\_r=1&ref=technology&gwh=2A3AFE019176F8F826296A37E4ED1BB8](http://www.nytimes.com/2012/01/19/technology/protests-of-antipiracy-bills-unite-web.html?_r=1&ref=technology&gwh=2A3AFE019176F8F826296A37E4ED1BB8).

<sup>268</sup> See Rory Cellan-Jones, Support Wanes in US Congress for Anti-Piracy Bill, BBC News, January 19, 2012, <http://www.bbc.co.uk/news/world-us-canada-16623831>.

<sup>269</sup> Wikipedia, SOPA initiative/Learn more, [http://en.wikipedia.org/wiki/Wikipedia:SOPA\\_initiative/Learn\\_more](http://en.wikipedia.org/wiki/Wikipedia:SOPA_initiative/Learn_more).

<sup>270</sup> Eric Engleman, Web Piracy Bills ‘Dead’ in U.S. From Lobbying, Dodd Says, Bloomberg, April 12, 2012, <http://www.bloomberg.com/news/2012-04-11/web-piracy-bills-dead-in-u-s-from-lobbying-dodd-says.html>.

***b. Legislation aimed at other prescription drugs online***

The Online Pharmacy Safety Act<sup>271</sup> (OPSA), currently under consideration in the Senate Health, Education, Labor, and Pensions Committee, addresses the online sales of prescription drugs not classified as controlled substances. The Act is narrower than the RHA, creating only two new requirements: (1) an in-person examination requirement for a valid prescription,<sup>272</sup> and (2) a registration requirement for all online pharmacies in a government registry.<sup>273</sup> Once the OPSA registry is created, the Act directs the dissemination of the “legitimate pharmacies” registry to the public and all Internet intermediaries.<sup>274</sup> Borrowing from the PIPA’s online pharmacy provisions, the OPSA then grants immunity to those intermediaries who refuse service to online pharmacies that are not listed by the registry.<sup>275</sup>

Although the OPSA does not enjoy RIAA’s lobbying dollars, neither is the legislation likely to meet the public opposition that derailed the PIPA’s course. The immunity provisions of the PIPA, aimed at rogue online pharmacies only, never surfaced in the public debates about the PIPA, indicating a lower public interest in the issue. The OPSA is co-sponsored by four

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<sup>271</sup> Senate Bill S. 2002, 112th Congress (2011). Text available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d112:SN02002>. The related bill in the U.S. House of Representatives is H.R. 4095.

<sup>272</sup> OPSA § 3.

<sup>273</sup> OPSA § 4.

<sup>274</sup> The OPSA lists the intended intermediary types in § 4(f)(1): “Internet advertising services, financial transaction providers, domain name registries, domain name registrars, other domain name authorities, information location tool service providers, and others as determined necessary and appropriate by the Secretary to promote public health and safety.”

<sup>275</sup> OPSA § 4(g).

Senators so far. Depending on the impact left by the failure of the PIPA, the legislation may gain bipartisan support as it progresses through the chambers.

As for the effect of the OPSA in regulating online pharmacies, the legislation is likely to aid the FDA significantly based on the same considerations that fueled the PIPA's immunity provisions – immunity implies obligations for the intermediaries, and thus effective federal oversight of the intermediaries' online pharmacy clients. Once the FDA establishes a “legal online pharmacy” registry, the burden shifts to the intermediaries to justify any online pharmacy clients who are not legally registered. By passing the burden to online pharmacies to register and to the Internet intermediaries to limit clients to registered pharmacies, the OPSA establishes the FDA as the regulator and the intermediaries as the enforcers of the new scheme, thus facilitating resource-efficient oversight.

### *c. New state laws that supplement federal law*

The active legislation drafting on part of the U.S. Congress did not stop the states from reaching online pharmacies through evolving state laws applicable to all pharmacies. Whereas federal efforts track the illegal drug sales by following the sources of drugs, states often tackle the activity from the opposite end – by investigating cases of drug abuse.

One of the most aggressive states on the issue has been Kentucky, where House Speaker and former State Attorney General Greg Stumbo has battled rogue online pharmacies and substance abuse for years. For several years, the state has employed the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system to track controlled substance prescriptions dispensed within the state, compiling a report by recipients, prescribers, and dispensers.<sup>276</sup> The

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<sup>276</sup> See Office of Inspector General, Kentucky Cabinet for Health and Family Services, What is KASPER?, <http://www.chfs.ky.gov/os/oig/KASPER.htm>. See also Ky. Rev. Stat. Ann. § 218A.202.

report is available to certain medical professionals and to some state authorities.<sup>277</sup> In April 2012, the Kentucky House of Representatives passed a House Bill 1, which tightens the regulation of controlled substances.<sup>278</sup> The bill's provisions include moving KASPER to the Attorney General's office, requiring all physicians who prescribe controlled substances to register with the attorney general, providing local authorities additional enforcement powers to track down diversion of controlled substances, requiring the Medicaid authority to track KASPER records, and increasing overall penalties for offenses involving controlled substances.<sup>279</sup> The law would establish an unprecedented, uniquely far-reaching enforcement system for controlled substances.

While states cannot handle the problem of rogue pharmacies on their own, the states' direct contact with the recipients of drugs plays an important role in the ongoing monitoring of rogue pharmacy activity in general, and the trafficking of controlled substances in particular. The proposed federal legislation may benefit from allocating some funding to similar state programs to share intelligence with the federal agencies.

## **6) CONCLUSION**

In the efforts to mitigate the growth of rogue Internet pharmacies, each actor—states, federal agencies, private intermediaries, and trade organizations—has proven effective in its realm, but

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<sup>277</sup> Ky. Rev. Stat. Ann. § 218A.202(6).

<sup>278</sup> An Act Relating to Controlled Substances and Making an Appropriation Therefor, House Bill 1, Kentucky 2012 Extraordinary Session, available at <http://www.lrc.ky.gov/record/12SS/HB1.htm>.

<sup>279</sup> Id.

inadequate to stop the overall trend. As policymakers and private companies continue to develop solutions to the Internet-based illegal drug sales, innovation and cooperation hold promise for success. The OSPA provides an example of a potent semi-voluntary engagement of Internet intermediaries. Kentucky serves as a pioneer in relying on the resources of the state to stop the demand for controlled substances. Visa, MasterCard, YouTube, and Craigslist, are all examples of quick notification-response procedures. Just as the rogue pharmacies rely on a network of intermediaries and suppliers to sell drugs illegally to U.S. residents, legitimate businesses and regulators are relying on each other to set up a powerful system of oversight.