

# **SYRACUSE SCIENCE AND TECHNOLOGY LAW REPORTER**

## **Buying Drugs over the Internet: Who is Regulating Pharmacies on the World Wide Web**

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### **I. INTRODUCTION**

Currently there is debate surrounding the benefits and risks of using internet pharmaceutical websites for purchasing prescription medications. One argument is that individuals are free to choose where they obtain medication. By allowing the market to control prices, free from excessive governmental interference, the result will be cheaper drugs for those who can least afford it. In contrast, another view is that internet pharmacies are riddled with fraud and abusive practices and that, in reality, drugs purchased over the internet are actually more expensive. Those who maintain this view advocate a unified federal system of oversight and accountability which will ensure that only safe pharmaceuticals enter the market.

This paper focuses on the individual who is attempting to access safe and quality medications at the lowest price. Several issues arise from focusing on the individual as opposed to the government's regulating of the industry. First, as an overview, what is an internet pharmacy, and how do they operate? Second, what are the benefits of buying drugs over the internet and what are the legal implications? Third, what levels of government currently regulate an individual's access to medication over the internet, and should this be reformed in order to benefit the individual buyers of medication? Fourth, what effect does current and proposed federal legislation have on an individual's ability to access cheap prescription drugs? Fifth,

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should the United States prohibit foreign pharmacies from selling medication over the internet to U.S. residents, and if so, is that even possible to regulate? Finally, what legal framework should be employed in light of the above discussion?

## II. INTERNET PHARMACIES: HOW DO THEY OPERATE

Internet sites that offer prescription drugs are legal in most states, but the ways in which they operate vary significantly.<sup>1</sup> In this age of cyberspace, consumers are frequently turning to the internet to get answers to medical questions.<sup>2</sup> Online pharmacies provide this information as well as offer prescription and non-prescription drugs which are sold over the internet and sent directly to the consumer.<sup>3</sup> According to the Pew Internet and American Life Project, one out of every four Americans today have ventured onto the World Wide Web in order to search for health related information and research prescription drugs.<sup>4</sup> The number of Americans that have actually purchased medication at an internet pharmacy is still relatively small, only four percent of the population, but the numbers have grown steadily over the years.<sup>5</sup> As more online consumers report satisfaction with their pharmaceutical purchases, the likelihood is that online pharmaceutical consumption will grow.<sup>6</sup> In response to the PEW Prescription Drugs Online

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<sup>1</sup> Julia Angwin, *Health: What's the Cure?*, WALL ST. J., December 9, 2002, at R6.

<sup>2</sup> *Internet Pharmacy Consumer Protection Act, Hearing on H.R. 3880 Before the House Comm. on Gov't Reform*, 108th Cong. (2004) [hereinafter *Hearings I*] (statement of William K. Hubbard, Assoc. Commissioner for Policy and Planning, U.S. Food and Drug Admin.), available at <http://www.fda.gov/ola/2004/internetdrugs0318.html> (last visited Nov. 9, 2005).

<sup>3</sup> *Internet Pharmacy Consumer Protection Act, Hearing on H.R. 3880 Before the House Comm. on Gov't Reform*, 108th Congress (2004) [hereinafter *Hearings II*] (statement of Craig Fuller, President, National Association of Chain Drug Stores), available at <http://www.nacds.org/wmspage.cfm?parm1=3554> (last visited Nov. 9, 2005).

<sup>4</sup> Susannah Fox, *Prescription Drugs Online*, PEW INTERNET AND AMERICAN LIFE PROJECT at 2 (October 2004), at [http://www.pewinternet.org/pdfs/PIP\\_Prescription\\_Drugs\\_Online.pdf](http://www.pewinternet.org/pdfs/PIP_Prescription_Drugs_Online.pdf) (last visited Nov. 9, 2005). (“Twenty-six percent of American adults have researched prescription drugs online – 21% have personally done so and 5% have had it done for them by someone else.”)

<sup>5</sup> *Id.* at 10.

<sup>6</sup> *Id.*

Survey, “[s]atisfied customer’s say they will return. Nine out of ten Americans who have purchased prescription drugs online say they plan to do so again.”<sup>7</sup> Unfortunately, not all online pharmacies are built the same, and consumers must be aware and knowledgeable of the internet sites they choose to visit. While the number of consumers grows, the government must also be mindful of the number and types of online pharmacies that emerge over the internet.<sup>8</sup>

Generally, there are three types of internet pharmacies. The first type of online pharmacy requires a prescription from a physician before an order for medication can be filled.<sup>9</sup> These sites are considered an extension of the traditional brick-and-mortar pharmacies.<sup>10</sup> Brick-and-mortar pharmacies are state licensed pharmaceutical stores which have chosen to create web sites as an extra convenience for their patients.<sup>11</sup> These brick-and-mortar pharmacies allow a patient to mail or fax in a prescription from a physician who has previously diagnosed the patient’s need for the prescription.<sup>12</sup> These types of internet sites verify the prescription, generally by contacting the physician, fill the prescription, and mail the medicine directly to the consumer.<sup>13</sup>

The second type of internet pharmacy does not require a consumer visit with a physician in their area. Instead, these sites employ physicians to consult with patients on their websites.

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<sup>7</sup> Fox, *supra* note 4, at 10.

<sup>8</sup> *Hearings I, supra* note 2.

<sup>9</sup> Fox, *supra* note 4, at 6. (The “vast majority of Rx purchasers say the site required a prescription and near majority of Rx purchasers say they had a prescription from their doctor.”)

<sup>10</sup> *Hearings II, supra* note 3.

<sup>11</sup> *Id.*

<sup>12</sup> Kerry Toth Rost, *Policing the “Wild West” World of Internet Pharmacies*, 55 FOOD & DRUG L.J. at 619 (2000).

<sup>13</sup> *Id.*

At these sites, a physician will often issue a prescription without ever examining the patient.<sup>14</sup> Where most physicians require a physical examination of the patient before they will write a prescription, on-line practitioners at these types of sites will issue prescriptions without establishing the traditional physician-patient relationship.<sup>15</sup> Generally, the patient merely has to fill out an online questionnaire, which is then reviewed by a physician employed by the site.<sup>16</sup> This physician will write a prescription based solely on the questionnaire.<sup>17</sup> The patient is only charged with a consultation fee if the physician prescribes medication.<sup>18</sup>

Finally, there are internet pharmaceutical sites which dispense drugs without requiring any type of prescription. These are often called ‘rogue’ pharmacies because they dispense medicine while bypassing all of the safeguards created to protect the patient.<sup>19</sup> Consumers searching for specific drug information may enter an internet site that will sell them the controlled substance without ever consulting a physician.<sup>20</sup> While the first type of online pharmacy operates in the same manner as your corner drug store, the second types pose certain hazards to consumer’s that are not aware or knowledgeable of the risks.

### **III. BENEFITS AND LEGAL IMPLICATIONS OF BUYING PHARMACEUTICALS ONLINE**

#### ***A. Benefits for Patients who choose to go online***

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<sup>14</sup> Jane E. Henney, M.D et al, *Internet Purchase of Prescription Drugs: Buyer Beware*, 131 ANNALS OF INTERNAL MED. 11, at 861 (1999).

<sup>15</sup> *Id.*

<sup>16</sup> Angwin, *supra* note 1, at R6.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Hearings II, supra* note 3. (“...rogue Internet sites...are engaged in a pattern of illegal activity regarding the prescribing and dispensing of prescription medications.”)

<sup>20</sup> *Hearings I, supra* note 2.

Convenience is the number one factor for ordering prescription drugs online.<sup>21</sup> Most internet sites that offer prescription drugs are retail pharmacies that have established websites out of convenience for their customers.<sup>22</sup> Internet users can easily access information and prescriptions for almost any drug sold on the market without having to leave their homes.<sup>23</sup> Internet pharmacies ship medications straight to a person's home, oftentimes, without a patient ever having to visit a physician's office.<sup>24</sup> Patients who choose to order prescriptions over the internet are able to avoid driving distances to go to their local pharmacy, long waits at the counter, and often are able to get prescriptions overnight through many providers.<sup>25</sup> Patients are also able to avoid the long waits that often come with setting up a doctor's appointment for non-emergency purposes.<sup>26</sup> Finally, comparative shopping over the Internet allows patients to conveniently choose the pharmaceutical website that offers the best prices without ever having to leave the comfort of their home.<sup>27</sup> It is this convenience that makes internet pharmacies attractive to many consumers. For example, seventy percent of the prescriptions filled by

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<sup>21</sup> Fox, *supra* note 4, at 6. ("...Americans who have ordered prescription drugs online are likely to cite convenience, time savings, and cost savings as the main reasons why they decided to take the leap. Privacy is the least likely factor of the four offered in the survey.")

<sup>22</sup> Rita Rubin, *Easier-to-Swallow Way to Get your Pills Refilled E-Pharmacies Offer Convenience but Raise Safety Concerns*, USA TODAY, Oct. 6, 1999, at 1D. ("Major Chains such as CVS and Walgreens, as well as independent drugstores, have staked their claims in cyberspace.")

<sup>23</sup> Benito Arrunada, *Quality safeguards and regulation of online pharmacies*, 13 HEALTH ECONOMICS 329, 331 (2003). ("Users enjoy greater availability in terms of opening hours, are able to substitute user travel by mail and can carry out comparative shopping, with a wider variety of products and enhanced access to product information and privacy.")

<sup>24</sup> Carl Bialik, *The Best Way To.....Fill Prescriptions*, WALL ST. J., Nov. 18, 2002, at R11.

<sup>25</sup> Rubin, *supra* note 22.

<sup>26</sup> James Ledbetter, *No Prescription, No Problem? Online Drugstores Don't Always Work the Way You'd Expect*, THE INDUSTRY STANDARD, available at <http://www.pcworld.com/news/article/0,aid,11633,00.asp> (posted June 30, 1999).

<sup>27</sup> Arrunada, *supra* note 23.

drugstore.com (a subsidiary of Rite Aid) are sent to patients with chronic health problems that require maintenance medications.<sup>28</sup> As a result, internet pharmacies tend to target those consumers who have chronic health conditions in order to maintain a customer base.<sup>29</sup> Internet pharmacies offer customers a convenient way to renew prescriptions, as well as to have their prescriptions mailed directly to them on a scheduled basis.<sup>30</sup>

In addition, internet pharmacies have capitalized on those consumer's who are embarrassed to discuss certain health problems with their physicians.<sup>31</sup> Internet pharmacists or physicians can discuss a consumer's health problem privately over the Internet without the embarrassment that comes with talking to the pharmacist in a brick-and-mortar establishment.<sup>32</sup> For example, Antopia.com is an internet site that provides various services for people with herpes or human papillomavirus (HPV).<sup>33</sup> While providing services such as community support and dating services, the site also provides several links to web sites that offer discount drugs which purport to cure the herpes virus.<sup>34</sup> By clicking on any of these links, individuals who might otherwise be embarrassed to consult face-to-face with a pharmacist can have these medications filled. The

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<sup>28</sup> Rubin, *supra* note 22.

<sup>29</sup> *Id.* (“Like its competitors, drugstore.com is targeting people who need maintenance medications, representing 70% of prescriptions...”)

<sup>30</sup> *Id.*

<sup>31</sup> Bialik, *supra* note 24.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*; Got Herpes.com Information Resources Community, at <http://www.gotherpes.com/> (n.d.)

<sup>34</sup> Antopia, *supra* note 33. (Advertisement links provided on the Antopia website include: Myskincare.com, Genisil.com, and Choraphor.com.)

patient looking for discretion when buying prescription drugs has found a haven in online pharmacies.<sup>35</sup>

### ***B. Legal Implications of Purchasing Drugs Online***

There are legal implications in exchange for the convenience of online pharmacies. According to Federal regulations, “[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>36</sup> This regulation reflects the public policy that “[a] practitioner’s supervision is essential to safe use of these [controlled] drugs.”<sup>37</sup> Therefore, Congress promulgated regulations, as well as similar statutes in all 50 states, that require a physician-patient relationship whenever prescriptions drugs are dispensed.<sup>38</sup> Generally, a physician-patient relationship is not established unless a physical examination is conducted, and a medical history of the patient is recorded.<sup>39</sup> While consumers may provide false information online as well as in a doctor’s office, the likelihood of misrepresentation by a patient is reduced when a doctor physically examines a patient and discusses their symptoms.<sup>40</sup>

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<sup>35</sup> See generally, Bialik, *supra* note 24.

<sup>36</sup> 21 C.F.R. § 1306.04 (2005).

<sup>37</sup> Henney, *supra* note 14, at 861-62.

<sup>38</sup> *Id.* at 861; Drug Enforcement Administration, *Frequently Asked Questions: Dispensing and Purchasing Controlled Substances over the Internet*, available at <http://www.deadiversion.usdoj.gov/faq/internetpurch.htm> (last visited Feb. 10, 2006).

<sup>39</sup> See generally, Drug Enforcement Administration, *supra* note 38.

<sup>40</sup> See generally, Henney, *supra* note 14.

No Physician Required:

Internet pharmaceutical websites that do not require any type of consultation with a physician pose serious risks to the patient.<sup>41</sup> When an internet site directly dispenses medication to a consumer, without establishing a physician-patient relationship, many of the safeguards established through ‘brick and mortar’ pharmacies are left behind.<sup>42</sup> In dispensing drugs directly to the patient, consumers are not provided with information they generally would receive from a physician or pharmacist.<sup>43</sup> Consumers may not be informed of possible side-effects, or harmful interactions that a drug may have with other medications the consumer is currently taking.<sup>44</sup>

Online Questionnaires:

Sites that utilize online questionnaires run the risk of harming patients for two main reasons: patients often lie when they fill out questionnaires, and the questionnaires do not ask enough questions to get the appropriate information necessary to proscribe a certain drug.<sup>45</sup> Also, many online questionnaires already have the answers pre-selected for consumers, which encourages consumers to provide incorrect information.<sup>46</sup> Patients are also more likely to lie on a questionnaire because they are embarrassed of their condition and because there is no physician available to observe the patient’s demeanor when answering questions.<sup>47</sup> Also, some of the

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<sup>41</sup> Arrunada, *supra* note 23.

<sup>42</sup> *Id.* at 331.

<sup>43</sup> Arrunada, *supra* note 23, at 335.

<sup>44</sup> *Id.*

<sup>45</sup> *See generally*, Angwin, *supra* note 1. *See also*, Smoak, *supra* note 45.

<sup>46</sup> Bernard S. Bloom & Ronald C. Iannacone, *Internet Availability of Prescription Pharmaceuticals to the Public*, 131 ANNALS OF INTERNAL MED. 11, 830, 833 (1999).

<sup>47</sup> *See supra* note 45.



terms used in online questionnaires may go beyond the technical knowledge of the average consumer.<sup>48</sup> Therefore, patients may not answer with certainty, and may provide misleading information on a questionnaire.<sup>49</sup>

Lifestyle Prescription Drug Sites:

Another problem is the *types* of drugs offered by “rogue” internet sites.<sup>50</sup> Many of the “rogue” internet sites offer ‘lifestyle’ drugs, including Prozac, Viagra, and hair loss medications.<sup>51</sup> Patients are lured to these sites because of the anonymity of the conversation.<sup>52</sup> Yet, it can be very dangerous to prescribe these types of drugs without establishing the traditional physician-patient relationship.<sup>53</sup>

For example, patients who order Viagra over the internet place themselves at risk if they have not seen a physician prior to ordering the drug online.<sup>54</sup> Erectile dysfunction “may occur because of multiple problems, including depression, diabetes, vascular problems or a pituitary tumor.”<sup>55</sup> A questionnaire will not reveal any underlying conditions a patient may have because many forms only ask for a patients’ medical history and symptoms. When a patient orders this

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<sup>48</sup> Smoak, *supra* note 45.

<sup>49</sup> *Id.*

<sup>50</sup> *See supra* note 19.

<sup>51</sup> James Ledbetter, *Is buying drugs on the Web too easy?*, CNN.com (June 29, 1999), at <http://edition.cnn.com/TECH/computing/9906/29/drugs.idg/>.

<sup>52</sup> *Id.*

<sup>53</sup> Henney, *supra* note 14, at 862. (“By avoiding the inconvenience of an office visit or overtly seeking to obtain a drug without having to see a practitioner (for example, an anorexic patient seeking a diet drug), a patient may sacrifice the opportunity for a correct diagnosis or identification of a contraindication of a drug.”)

<sup>54</sup> Barry Yeoman, *Drugs Online: A New Danger*, LADIES HOME JOURNAL (last visited 11/18/2004), at <http://lhj.com/lhj/story.jhtml?storyid=/templatedate/lhj/story/data/16196.xml>.

<sup>55</sup> *Id.*

drug online, they are missing the opportunity to talk to a licensed physician and possibly uncover the seriousness of his actual condition.<sup>56</sup>

Not only does the patient not get necessary medical advice from a qualified physician at many internet pharmacies, but the patient also misses the next line of defense: the qualified pharmacist.<sup>57</sup> Without speaking to a licensed pharmacist, patients may never get information concerning a drug's proper use, potential side effects, or drug interactions.<sup>58</sup>

#### IV. STATE REGULATION OF INTERNET PHARMACIES

While a unified national regulatory system over online pharmacies may seem beneficial, States currently retain the power to license both physicians and pharmacists.<sup>59</sup> Under the current system, physicians and pharmacists must obtain a license by the state to practice medicine.<sup>60</sup> Physician and pharmacists may only practice in those states where they are licensed.<sup>61</sup> While physicians can get licensed in more than one state, it is an arduous process and few physicians endeavor to do so.<sup>62</sup> Also, according to the American Medical Association and the Federation of

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<sup>56</sup> Yeoman, *supra* note 54.

<sup>57</sup> Rost, *supra* note 12, at 623.

<sup>58</sup> See Arrunada, *supra* note 23, at 332-32. ("Twenty-two pharmacies [were] identified in a more specific study that aimed to estimate to what extent Viagra was being sold via the internet for patients with contra-indications, 2 required a written prescription from a doctor, 9 dispensed Viagra without a prescription at all, and 11 issued an 'online prescription' after a so-called 'doctor' had examined a clinical questionnaire. The simulated purchaser was a woman aged 69, with difficulty in experiencing orgasm, obesity, coronary insufficiency and high blood pressure and who was taking [several prescriptions with extreme side-effects if taken with Viagra]. She requested 66 pills from 10 of the 11 pharmacies requiring a questionnaire... Three of these companies sold the pills, in spite of the serious contraindications, and seven rejected the order.")

<sup>59</sup> See generally, *Hearings I*, *supra* note 2; *Hearings II*, *supra* note 3. ("State Boards have effectively regulated the practices of medicine and pharmacy for more than 100 years.")

<sup>60</sup> Rost, *supra* note 12.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 626.

State Medical Boards, a licensed physician may not prescribe medication unless a physician-patient relationship exists.<sup>63</sup>

Because physicians and pharmacists are currently regulated by the states where they are licensed, a two-fold problem has arisen with regulating online pharmacies.<sup>64</sup> First, what constitutes a physician-patient relationship and is a physical examination by a physician necessary to establish such a relationship?<sup>65</sup> Second, what system or agency should regulate and oversee Internet pharmacies if the States are not capable with coming up with a consensus to the above questions?<sup>66</sup>

**A. *The American Medical Association Model for Online Prescribing***

While the American Medical Association (AMA) does not have the authority to regulate medical practices within states, it is influential in promoting standards of practice.<sup>67</sup> The AMA has made recommendations on how to determine when prescribing medicine over the Internet may be appropriate.<sup>68</sup> Under the AMA model, before writing a prescription for medication, a physician must: 1) Have access to the patient's medical history; 2) discuss the specific treatment and any alternatives to such proposed treatment; 3) inform the patient of the benefits and the risks to the proposed medication; 4) perform a physical examination of the patient, and; 5) when

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<sup>63</sup> *Internet Prescription Drugs: Before the House Comm. on Gov't Reform*, 108th Congress (2004) [hereinafter *Hearings III*] (statement of Rebecca J. Patchin, M.D. Trustee, American Medical Association), available at <http://reform.house.gov/UploadedFiles/AMA%20-%20Patchin%20Testimony.pdf>.)

<sup>64</sup> See Rost, *supra* note 12, at 626.

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> See *Drugstores on the Net: The Benefits and Risks of On-line Pharmacies Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. (1999) [hereinafter *Commerce Hearings I*] (statement of Dr. Herman Abromowitz, American Medical Association).

<sup>68</sup> *Id.*

necessary, provide additional treatment and physician visits where the medication may have serious side effects.<sup>69</sup>

In making these regulations, the AMA has *not* indicated that there is no time when a physician may prescribe medication over the Internet, just that they are limited to the instances where a legitimate physician-patient relationship exists.<sup>70</sup> Such instances include when a patient uses an internet pharmacy to refill a prescription.<sup>71</sup> According to the AMA, a physician-patient relationship is not established if: 1) there is no adequate examination of the patient in order to determine if a medical problem exists; 2) there is no actual communication between the patient and a physician in order to discuss alternatives and the risks of a proposed treatment or medication; 3) there is no attempt by the internet physician to obtain a patient's medical history, and; 4) there are no systems which provide for follow-up care or supervision of a patient.<sup>72</sup>

Whether a legitimate physician-patient relationship has been established is not as clear for Internet sites where a physician is merely a consultant and does not have any physical contact with the consumer seeking medical attention.<sup>73</sup> In response to the concern that patients may be harmed when a physician-patient relationship is not present, the AMA adopted the position in 1999 that any physician that prescribes medication to a patient based *solely* on an online questionnaire has generally not met the appropriate medical standard of care.<sup>74</sup> While the AMA acknowledges that a physician may make “clinical decisions” without physically seeing a

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<sup>69</sup> *Commerce Hearings I, supra* note 67.

<sup>70</sup> *Hearings III, supra* note 63.

<sup>71</sup> *See Commerce Hearings I, supra* note 67.

<sup>72</sup> *Hearings III, supra* note 63.

<sup>73</sup> *See Commerce Hearings I, supra* note 67.

<sup>74</sup> Smoak, *supra* note 45; Henney, *supra* note 14, at 861-62.

patient, such decisions should not be made unless the patient and physician have an ongoing relationship.<sup>75</sup> Clinical decisions may be made by a physician over the Internet as long as the “patient routinely uses [the] physician, and history and physical information are already in the medical record.”<sup>76</sup> Merely answering questions on an Internet pharmacy site does not constitute such a continuing relationship.<sup>77</sup>

### **B. Recent State Action and Regulations**

The Food and Drug Administration, as well as several states, have taken action against physicians who have prescribed drugs without first establishing a physician-patient relationship.<sup>78</sup> Several states have attempted to regulate and discipline the actual online pharmaceutical websites that do not require a physician-patient relationship before distributing medication.<sup>79</sup> Yet, clamping down on these companies is generally done on an ad hoc basis, and there is no consensus among the states on how to deal with the problem.<sup>80</sup> Several states, including Kentucky and Oklahoma, have passed statutes banning physicians from writing online prescriptions without first conducting a physical examination of the patient.<sup>81</sup> Yet, most other states have only gone as far as having the state medical boards promulgate guidelines indicating that prescribing medication without physical examinations is considered below the general

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<sup>75</sup> Smoak, *supra* note 45.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*; see also Drug Enforcement Administration, *supra* note 38. (“It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate doctor/patient relationship, and it is unlikely for such a relationship to be formed through internet correspondence alone.”)

<sup>78</sup> Henney, *supra* note 14, at 861-62.

<sup>79</sup> Angwin, *supra* note 1.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*; OKLA. STAT. ANN. tit. 59, § 492 (2005); KY. REV. STAT. ANN. § 218A.180 (2004).

standard of medical care.<sup>82</sup> The problem with these guidelines and statutes is that states can only enforce rules and discipline physicians that are practicing within their borders.<sup>83</sup> A state may not sanction or discipline physicians who are not licensed within the state.<sup>84</sup> Similarly, pharmacists pose regulatory problems because they can only be disciplined by the State they are licensed to practice in.<sup>85</sup> Therefore, if a state disciplines or revokes a physician or pharmacist's license, the website itself is not necessarily shut down<sup>86</sup>. The website may still operate within other states without fear.<sup>87</sup>

Yet, several states have successfully prosecuted physicians and pharmaceutical web sites. Generally, states have succeeded in these suits based on two causes of action. First, states have successfully prosecuted physicians who proscribed medication without examining a patient, in violation of a *specific* state law.<sup>88</sup> Second, physicians and pharmaceutical websites are prosecuted for selling controlled substances to consumers within their state without having a

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<sup>82</sup> Angwin, *supra* note 1.

<sup>83</sup> *Id.* (“...because regulators can’t enforce rules beyond their state boundaries, their actions often lack teeth. If one state revokes a physician’s or pharmacy’s license, for example, the Web site can usually still operate in other states.”)

<sup>84</sup> *See generally*, Rubin, *supra* note 22.

<sup>85</sup> *Hearings I*, *supra* note 2; *See also* Rubin, *supra* note 22 (All states regulate who can fill prescriptions, and pharmacists who fill prescriptions for a consumer in a particular state are supposed to be licensed within that state. “Because the Internet knows no geographical boundaries, it presents unique challenges to regulatory and law enforcement authorities.”)

<sup>86</sup> Angwin, *supra* note 1.

<sup>87</sup> *Id.*

<sup>88</sup> *See* Ledbetter, *supra* note 26; Ledbetter, *supra* note 51. (State law enforcement in California shut down two web sites – [www.drpropecia.com](http://www.drpropecia.com) and [www.deyarmanmedical.com](http://www.deyarmanmedical.com) – run by a San Diego osteopath who was prescribing Propecia for baldness without ever examining his patients.); *see also* Missouri Attorney General Press Release, *Nixon Obtains Order to Stop Illegal Internet Prescribing and Sale of Drugs by Second Online Clinic and Pharmacy*, available at <http://www.ago.mo.gov/newsreleases/1999/112999.htm> (Nov. 29, 1999) (the Missouri Attorney General obtained a permanent injunction against an online clinic that was selling prescription drugs to consumers in Missouri. Missouri fined the defendants \$15,000 in civil penalties for violating Missouri state law which prohibits the selling of prescription drugs without a license *and* based only on an online consultation).

*valid license* to sell such substances within the state.<sup>89</sup> These successes have resulted in a range of sanctions, from mere letters of censure to severe jail sentences.<sup>90</sup> Yet, while a state can revoke a physician or pharmacist's license or fine a website, this does not generally prevent the host website from operating in other states.<sup>91</sup>

## V. SELF-REGULATION OF INTERNET PHARMACIES

Another source of regulation proffered by several internet pharmacies is self-regulation.<sup>92</sup> The National Association of Boards of Pharmacy (NABP) is concerned with working with state medical boards to develop uniform standards to protect the public health.<sup>93</sup> In promoting this goal, NABP does not believe that further federal or state legislation is necessary to control online pharmacies.<sup>94</sup> Instead, NABP focuses on promoting cooperation between legitimate pharmacies and state medical boards in order to ensure that consumers are provided safe medication when bought over the internet.<sup>95</sup>

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<sup>89</sup> See Rost, *supra* note 12, at 632-33. (The "Illinois Attorney General and the Illinois Department of Professional Regulations filed four lawsuits against out-of-state doctors, pharmacies, and Internet-based companies. Illinois alleges the doctors and pharmacies were not licensed to operate and that the websites failed to disclose that the sites were not licensed to serve Illinois consumers.")

<sup>90</sup> Rost, *supra* note 12, at 626 n.77, 632 n.154. (Colorado merely sent a letter reprimanding a Colorado physician for selling Viagra online without conducting examinations, while Illinois charged physicians, pharmacies and web-based companies fines starting at \$50,000 *per* transaction after selling drugs within the state without a license.)

<sup>91</sup> *Hearings I*, *supra* note 2.

<sup>92</sup> John Barry, *Online Pharmacies: Should We Be Free to Buy Drugs Without the Advice of a Doctor?* available at [http://speakout.com/activism/issue\\_briefs/1339b-1.html](http://speakout.com/activism/issue_briefs/1339b-1.html) (posted June 15, 2000).

<sup>93</sup> National Association Boards of Pharmacy, *Verified Internet Pharmacy Practice sites (VIPPS); Information and Verification Site* available at <http://www.nabp.net/vipps/intro.asp> (last modified Jan. 12, 2006).

<sup>94</sup> National Association Boards of Pharmacy, *Verified Internet Pharmacy Practice sites (VIPPS); Most Frequently Asked Questions* available at <http://www.nabp.net/vipps/consumer/faq.asp> (last modified Sept. 21, 2004).

<sup>95</sup> *Id.*

In 1999, NABP created the Verified Internet Pharmacy Practice Sites (VIPPS) certification program, which provides consumers with information about online pharmacies.<sup>96</sup> The VIPPS program helps consumers identify “those online pharmacy practice sites that are appropriately licensed, [and] are legitimately operating via the Internet, and that have successfully completed a rigorous criteria review and inspection.”<sup>97</sup> While NABP does not have the authority to regulate internet pharmacies, those sites that seek the VIPPS seal of approval must meet certain criteria.<sup>98</sup> To become a VIPPS certified online pharmacy, the pharmacy must comply with all the licensing requirements within the state where the pharmacy is located *and* in each state where the pharmacy plans to distribute pharmaceuticals. Also, pharmacies must also demonstrate “compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.”<sup>99</sup> Internet sites with the VIPPS seal of approval are legitimate internet pharmaceutical sites and the companies that run these sites are generally weary of further governmental regulation.<sup>100</sup> While the VIPPS program is a first step at legitimate self-regulation of internet pharmaceutical sites, the vast amount of ‘rogue’ sites appearing on the internet everyday must be curtailed with some form of regulation.<sup>101</sup>

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<sup>96</sup> National Association Boards of Pharmacy, *supra* note 94.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> *Hearings II*, *supra* note 3; *see also* National Association Boards of Pharmacy, *supra* note 93.

<sup>100</sup> Barry, *supra* note 92.

<sup>101</sup> *Id.*



## VI. FEDERAL REGULATION OF INTERNET PHARMACIES

### A. *Current Federal Regulations*

The federal government currently regulates the dispensing of prescription drugs by physicians and pharmacists under the Controlled Substances Act and the Federal Food Drug and Cosmetic Act (FFDCA)<sup>102</sup>. The FFDCA categorizes certain drugs as prescription and non-prescription pharmaceuticals.<sup>103</sup> Under this Act, the Food and Drug Administration (FDA) was given authority to control the dispensing of prescription drugs, limiting dispensing to consumers who have a *valid* prescription by a licensed physician.<sup>104</sup> Through this Act, Congress mandated that some form of physician-patient relationship exist before a patient can obtain a valid prescription for a controlled substance.<sup>105</sup> Also, according to 21 CFR 1306, in order for “a prescription for a controlled substance to be effective [it] must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”<sup>106</sup> Proper prescribing and dispensing of medication is considered the responsibility of the physician as well as the dispensing pharmacist under federal law.<sup>107</sup> Under the Food, Drug and Cosmetic Act, the FDA has the authority to take action against companies, physicians or pharmacists that:

- 1) import, sell, or distribute adulterated or misbranded drugs;
- 2) import, sell, or distribute an

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<sup>102</sup> Controlled Substances Act, 21 U.S.C. §801, 829 (2004); Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. § 301 (2004).

<sup>103</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. § 301 (2004).

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*; see also 21 C.F.R. 1306.04(a) (2004) (Under federal law, “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.” The usual course of a physician’s professional practice is characterized by forming physician-patient relationships.)

<sup>106</sup> 21 C.F.R. § 1306.04 (2004).

<sup>107</sup> *Id.* (Those who knowingly fill prescriptions *not* in the usual course of professional practice are subject to penalties.)

unapproved new drug; 3) illegally promote a drug; 4) sell or dispense a prescription drug without a valid prescription, and; 5) counterfeit drugs.<sup>108</sup>

While the Controlled Substance Act and the Food, Drug and Cosmetic Act seem to require the establishment of a physician-patient relationship before the dispensing of prescription medications, this requirement is almost impossible to enforce in relation to internet pharmacies.<sup>109</sup> Such regulations have had little effect over illegitimate, rogue internet pharmacy sites due to the “broad reach, relative anonymity, and ease of creating new or removing old websites” on the internet.<sup>110</sup> According to the FDA, rogue sites are difficult to monitor and require mass resources because the sites are generally comprised of multiple links and are more complex and difficult to track than legitimate pharmaceutical websites.<sup>111</sup> Law enforcement is hindered due to the global nature of the internet.<sup>112</sup> Therefore, the FDA currently focuses much of its resources on sellers of “illegal foreign pharmaceuticals” and the sale of non-FDA approved drugs over the internet.<sup>113</sup>

***B. Proposed Federal Legislation: The Internet Pharmacy Consumer Protection Act***

One attempt by the federal government to regulate internet pharmacies is the proposed legislation entitled the Internet Pharmacy Consumer Protection Act (H.R. 3880).<sup>114</sup> Generally,

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<sup>108</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. § 301 (2004).

<sup>109</sup> *Hearings I*, *supra* note 2.

<sup>110</sup> *Id.*

<sup>111</sup> *Id.* (“FDA has found that many Internet sites are actually comprised of multiple related sites and links, thereby making investigations much more complex and resource intensive.”)

<sup>112</sup> *Id.* (“The global nature of the Internet creates special problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for U.S. officials.”)

<sup>113</sup> Rost, *supra* note 12, at 627.

<sup>114</sup> Internet Pharmacy Consumer Protection Act, H.R. 3880, 108th Cong. (2004).

this Act would “amend the Federal Food, Drug, and Cosmetic Act with respect to the sale of prescription drugs over the internet.”<sup>115</sup> First, the Act would prohibit the dispensing and sale of drugs over the internet by any person if the internet site failed to meet specific requirements, including providing the identities and licensing information of the seller, pharmacists, or medical consultants.<sup>116</sup> Second, the Act would prohibit the sale of prescription drugs: 1) if the consumer did not enter the site already armed with a valid prescription from a qualified physician, 2) if a practitioner provided by the internet site issued a prescription for the drug purchased by the consumer, and 3) if no “qualifying medical relationship” existed.<sup>117</sup> Under the Act, a qualifying medical relationship would require that a patient have “at least one in person medical evaluation...conducted by a practitioner.”<sup>118</sup> An in-person medical evaluation requires that the physician be in the physical presence of the patient when conducting an examination. The purpose of the Act is to require that a physician-patient relationship be formed before any prescription drugs are sold over the internet. The Act also attempts to prohibit sites that do not identify which states the physicians and pharmacists are licensed to dispense pharmaceuticals, and the credentials of the seller.<sup>119</sup>

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<sup>115</sup> Internet Pharmacy Consumer Protection Act, H.R. 3880, 108th Cong. (2004).

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.* (Each page of each site must include: 1) the name, address, and telephone number for the principal place of business for the seller of the prescription drugs, 2) the State in which the physician or pharmacist is authorized to dispense or prescribe pharmaceuticals, and; 3) the name of the physicians who provide consultations for the site and the states in which the physician is licensed to practice medicine.)

In addition to authorizing the FDA to take action against violators, the Act also allows state governments to bring civil actions against persons who are in violation.<sup>120</sup> It is the intention, according to the FDA, that this Act would encourage the cooperation between federal and state law enforcement agencies.<sup>121</sup> Yet, other organizations, specifically the National Association of Boards of Pharmacy, argue that the Internet Pharmacy Consumer Protection Act is redundant, especially for pharmacies that already self-regulate and have acquired the VIPPS seal of approval.<sup>122</sup> Also, many pharmacies are concerned that federal regulation of internet pharmacies will have unforeseen consequences on all traditional “brick-and-mortar pharmacies.”<sup>123</sup> In order to prevent such consequences, the National Association of Chain Drug Stores suggests that any federal legislation should specifically distinguish between brick-and-mortar pharmacies that also offer web services with those that operate exclusively over the internet.<sup>124</sup>

## **VII. COST SAVINGS AND THE CURRENT BAN ON FOREIGN PHARMACEUTICALS**

### ***A. Consumer’s Benefit from Price Savings found Online***

One of the largest draws to internet pharmacies for consumers is the potential for saving money on the cost of prescription drugs.<sup>125</sup> “An indisputable advantage of shopping online [is that] it is more convenient to compare prices among Internet pharmacies than among

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<sup>120</sup> Internet Pharmacy Consumer Protection Act, H.R. 3880, 108th Cong. (2004).

<sup>121</sup> U.S. Food and Drug Administration, *Online Pharmacy FAQs*, (Jan. 2000) available at <http://www.fda.gov/oc/buyonline/prfaqs.html>.

<sup>122</sup> *Hearings II*, *supra* note 3.

<sup>123</sup> *Id.* at 2.

<sup>124</sup> *Id.*

<sup>125</sup> Bialik, *supra* note 24.

brick-and-mortar kind.”<sup>126</sup> Pharmacies argue that they are able to offer prescription drugs at cheaper prices because of bulk orders and efficiencies of scale.<sup>127</sup> The cost of online drugs is especially reduced if patients buy the drugs from a foreign versus American site. Specifically, drugs ordered from Canadian Internet pharmacies offer savings often equaling 80% compared to American prices.<sup>128</sup> Canadian pharmaceuticals are cheaper because the government has placed price caps on most prescription drugs.<sup>129</sup> In 2003, Americans bought almost \$1.1 billion of Canadian drugs.<sup>130</sup> This figure is only likely to rise as Americans without prescription drug coverage realize the cost benefits that can be utilized from these Canadian internet sites.<sup>131</sup>

While the FDA and other regulatory agencies have focused much of their resources on preventing foreign pharmaceuticals from entering the United States, there is an argument for fostering this industry. For example, the Canadian International Pharmacy Association (CIPA) has recently released a “Safe List” which confirms the legitimacy of a Canadian pharmaceutical website.<sup>132</sup> This website provides links to Canadian pharmacies that have been verified by the organization.<sup>133</sup> Each member of the “Safe List” must provide information including their

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<sup>126</sup> Bialik, *supra* note 24.

<sup>127</sup> *Id.*

<sup>128</sup> Kelly K. Spors, *Canadian Drugs are Getting Cheaper: Online Pharmacies Catering to Americans Cut Costs By Finding New Suppliers*, WALL ST. J., July 22, 2004, at D1.

<sup>129</sup> Patented Medicine Prices Review Board, *Frequently Asked Questions* (last visited 11/18/2004), at <http://www.pmpbr-cepmg.gc.ca/english/view.asp?x=272&pf=1>. (Under the 1987 Patent Act, Canada set up the Patented Medicine Prices Review Board which “limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure that [prices] are not excessive.”)

<sup>130</sup> Spors, *supra* note 128.

<sup>131</sup> *See Id.*

<sup>132</sup> CIPA ‘Safe List’ Offers Peace of Mind to Prescription Drug Purchasers, PR NEWSWIRE, Oct. 12, 2004, available at <http://serv.prnewswire.com/health-care-hospitals/20041012/CLTU03012102004-1.html>. (“[CIPA] is a non-profit trade association created in 2002 to represent leading Canadian Mail order pharmacies.”)

<sup>133</sup> *Id.*

“provincial pharmacy license” and “disclosure [of] a drug’s country of origin.”<sup>134</sup> As more foreign countries develop systems that ensure adequate disclosure of quality standards and pharmaceutical information on websites, Americans may begin to trust foreign pharmaceutical companies and reap the benefits of cheaper prescription drugs.<sup>135</sup>

***B. Current Regulation of Foreign Pharmaceuticals and the Effect on Consumers***

Banning foreign drugs helps safeguard consumers from buying low quality pharmaceuticals, but at the expense of promoting competition and cheaper drugs on the market. For example, Canada and other foreign countries are often able to offer generic and name brand drugs at cheaper prices.<sup>136</sup> Yet, under current regulations, the FDA bans the shipment of all foreign drugs into the United States, with few exceptions.<sup>137</sup> Controlled substances may not be shipped to the US from foreign markets unless the “purchaser is registered with DEA [Drug Enforcement Administration] as an importer.”<sup>138</sup> Under the Controlled Substances Act, only persons who have been specifically authorized by the Attorney General may import controlled substances.<sup>139</sup> The illegal importation of controlled substances is a felony.<sup>140</sup> The FDA argues

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<sup>134</sup> *CIPA ‘Safe List’ Offers Peace of Mind to Prescription Drug Purchasers*, *supra* note 132.

<sup>135</sup> *See Spors*, *supra* note 128; *See also Fox*, *supra* note 4. (“Seventy-one percent of Americans agree with [the]...statement: ‘Others argue that people should not be allowed to purchase prescription drugs online because not all pharmacies are licensed in the United States, and there’s no way to guarantee the safety of drugs that come from other countries.’”)

<sup>136</sup> Bialik, *supra* note 24.

<sup>137</sup> 21 U.S.C.S. § 952 (2005); 21 U.S.C.S. § 957 (2005).

<sup>138</sup> Drug Enforcement Administration, *supra* note 38; *See also supra* note 10.

<sup>139</sup> 21 U.S.C.S. § 952 (2005); 21 U.S.C.S. § 957 (2005).

<sup>140</sup> 21 U.S.C.S. § 960 (2005).

that there are inadequate safeguards on the quality of imported drugs, and that no effective system of allowing only quality drugs into America has been developed.<sup>141</sup>

This ban on the importation of foreign pharmaceuticals places a huge burden on the elderly and those who are uninsured, who otherwise might have access to cheaper medication over the internet.<sup>142</sup> For example, an elderly diabetic who had recently lost his insurance was encouraged to buy his medication over the internet from a Canadian website.<sup>143</sup> The cost of a 90 day prescription from the Canadian website came to \$59 compared to \$251 from an American pharmacy.<sup>144</sup> Yet, until there are safeguards in place, there is no guarantee that the drugs a person purchases over the internet are safe. Prescription drugs purchased at foreign pharmaceutical websites have a much higher likelihood of contamination or counterfeiting of the product advertised.<sup>145</sup>

## VIII. CONCLUSION

### A. *Who should Regulate Internet Pharmacies*

The final question posed by this note is which level of government should be charged with regulating Internet pharmacies: the federal government or individual states? *Opponents* of federal regulation argue that federal involvement will hinder the pharmaceutical industry's growth. They argue that reducing federal involvement will benefit the consumer by encouraging growth within the industry which will inevitably result in cheaper drugs for the average

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<sup>141</sup> Bialik, *supra* note 24.

<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> Henney, *supra* note 14, at 861-62.

consumer.<sup>146</sup> In addition, many pharmacies believe that federal involvement will lead to the overall federal regulation of the practice of medicine, stripping control currently held by the states.<sup>147</sup>

Yet, on the other hand, *proponents* of federal involvement argue that the individual states are not equipped to deal with the unique challenges internet pharmacies bring.<sup>148</sup> If each state attacks the problem in a piecemeal fashion, the process of closing down illegitimate and potentially harmful websites could take years.<sup>149</sup> Yet, if the federal government were to prohibit a certain pharmaceutical website from conducting business, then such websites could no longer merely re-establish business in another state.<sup>150</sup>

I recommend that the solution lies with both sides of the argument. In order to protect the consumer's while also maintaining state control over the practice of medicine, states should continue to regulate, but in cooperation with federal law enforcement.

### ***B. The Future of Internet Pharmacies under a Cooperative Regulation Scheme***

While monitoring internet pharmacies is necessary, they should not be regulated, by the state *or* federal government, to the point of dissolving all of the benefits that attract individuals to them in the first place: namely convenience and cost savings. While self-regulation by the pharmaceutical companies themselves may seem an attractive option, it only eradicates part of the problem. New illegitimate websites are constantly showing up on the internet with the

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<sup>146</sup> Henney, *supra* note 14, at 861-62.

<sup>147</sup> *Id.*

<sup>148</sup> *See generally, Risks Demand Greater Oversight.* USA TODAY, Jan. 3, 2000, at 18A. (Some states are concerned that their own law enforcement agencies are not equipped to investigate and prosecute 'rogue' internet pharmacies.)

<sup>149</sup> Hubbard, *supra* note 2.

<sup>150</sup> *Id.*



specific intention of providing false information to the public about pharmaceuticals and are a health risk to society. Under the current state-regulated licensing system, there is little incentive for these ‘rogue’ sites to self-regulate. As one state prosecutes the internet pharmacy, the pharmacy may begin the next day illegally selling pharmaceuticals in another state.

Online pharmacies, therefore, must be controlled and regulated, to some extent, under a unified system, in order to ensure the safety of the consumers purchasing the drugs over the internet. While the States should remain in control over licensing physicians and pharmacists within their own states, the Federal government should devise regulations to control the information that is published on the web. On one hand, the individual states should continue to require a physician-patient relationship prior to the dispensing of prescription drugs, and on the other, the Federal government should guarantee and keep track of the information disclosed on pharmaceutical websites. Therefore, when a state official receives a complaint about an illegitimate internet pharmacy, the physicians, pharmacists and sellers of the prescription drugs can be identified by the federal government. If there is not a national system of identifying who and where ‘rogue’ pharmacies are being run, then there is little hope that the individual state will have the power to crack down on them. Such a system requires cooperation between the state and federal government, but allows each level of government to control that which they have the resources and expertise to implement.

When determining a system of oversight, the best interests of consumers should remain the central focus of the debate. Patients must be protected from the hazards that illegitimate websites pose; yet, the growth of legitimate websites should be encouraged. This goal can be met only if the states and the Federal government cooperate. The Federal government has the power to reach those internet sites that are located outside of the United States, as well as those

that cross state boundaries. Therefore, the Federal government must be charged with eliminating 'rogue' internet pharmacies. On the other hand, it is important to consider that individual state governments have been charged with regulating the licensing of physicians and pharmacists for generations. As a result, the standards and practices of different states must be respected, and should not be overcome by overzealous federal control. Such control will hinder the growth of legitimate pharmaceutical sites if they are subject to extensive federal oversight. If the best interest of the consumer is to remain the focal concern, then the States and Federal government must cooperate, and use their specific expertise and resources to create a safe and honest environment for the next generation of online consumers.