REGULATING ROGUE PHARMACIES USING RFID TAGS, 2D BARCODES, AND BIOMETRICS

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I. INTRODUCTION ....................................................................................72
II. DIFFERENT TYPES OF INTERNET PHARMACIES ...................................74
III. BENEFITS OF INTERNET PHARMACIES ...............................................75
IV. STATE REGULATION .............................................................................77
V. INDUSTRY SELF REGULATION ..............................................................79
VI. FEDERAL REGULATION ........................................................................80
   A. Controlled Substances Act and Food and Drug Cosmetic Act ................80
   B. Safe Internet Pharmacy Act of 2007 and Ryan Haight Online Pharmacy Consumer Act of 2007 ..................81
   C. Reducing Fraudulent and Imitation Drugs Act of 2007 ........83
   D. United States Food and Drug Administration RFID Workgroup .....................85
V. RFID AND 2D BARCODES OVERVIEW .................................................86
   A. Advantages and Disadvantages of Implementing RFID and 2D Barcode Technology ................88
VI. BIOMETRICS OVERVIEW .....................................................................91
   A. Advantages and Disadvantage of Implementing Biometric Technology ........93
VII. CONCLUSION ......................................................................................95

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I. INTRODUCTION

Internet pharmacies provide a convenient as well as inexpensive way to purchase prescription medicines. However, some sites have put consumer health at risk by not only dispensing counterfeit drugs but also offering them without a valid prescription. More than ever, Americans are turning to the Internet for their medication needs, as demonstrated by a recent survey conducted in 2007 by the Manufacturers of America which revealed that internet pharmacies were used in 31 percent of pharmaceutical purchases. American consumers are drawn to the Internet because of the relative ease of ordering and filling prescriptions without having to leave the house, as well as increased privacy.

Many regulatory issues have arisen from illegal sites that provide drugs without a prescription or consultation with a physician—mainly because half of these sites ship drugs from foreign countries. A 2007 study conducted by the National Center on Addiction and Substance Abuse at Columbia University found that 48 percent of the medications purchased from an Internet site selling prescription drugs are shipped from a foreign country, compared to 26 percent that are shipped from an American pharmacy. The United States has attempted to secure the drug supply in America through federal and state regulation and industry regulation; however, the United States often cannot extend its jurisdiction to

3 Alexander, supra note 1, at 2-3; see also 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 (2004) (those who seek treatment through online pharmacies benefit from the increased privacy that online pharmacies provide.).
5 Pharmaceutical Drugs, supra note 2.
these foreign pharmacies providing the drugs. Therefore, these pharmacies often proceed unregulated and free to send drugs to any consumer accessing their sites. The legislation that has been introduced in the Senate and the House of Representatives applies only to those Internet pharmacies operating within the United States. States are also attempting to address this problem by prosecuting pharmacists and online pharmacies that mail out drugs without a prescription or consultation.

The use of new technology such as radio frequency identification (RFID), 2D barcodes, and biometrics can assist in the regulation of Internet pharmacies nationally as well as internationally by assisting with inventory control and tracking where the drugs go after they leave the pharmaceutical companies. The goal of using RFID tags and 2D barcodes is to expose the location of the foreign drug supply sources which have previously been protected by the anonymity of the Internet. This may allow U.S. pharmaceutical companies and drug enforcement agencies to enlist the help of law enforcement agencies in these foreign countries for assistance with regulation. Furthermore, biometric technology could be used as a method to verify the identity of the recipient of the

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6 Yoo, supra note 4, at 59.
7 Id.
8 See Patrick J. Egan, Internet Pharmacy: Gray Area With Big Profit and High Risks, 29 CHAMPION 32, 34 (Dec. 2005). (Note: entering this cite on WL takes you to a page where you can choose this article. So when you type this cite in, you get three different citation options and you can click this one.).
9 Texas State Board of Pharmacy Newsletter (Spring 2004), available at http://www.tsbp.state.tx.us/newsletter/InternetPharmacies17.htm (setting forth guidelines that pharmacists must follow before dispensing a prescription, including making sure the patient has a valid prescription as well as a the existence of a patient-physician relationship) [hereinafter Newsletter]; see also Ancier v. State Dep't of Health, 166 P.3d 829, 833 Wash. App. 564 (2007). This case involved a pharmacist who prescribed medications over the Internet without engaging in a proper diagnosis. Id. at 833. The court held that it posed an "unreasonable risk of harm" to patients and constituted a violation of the Uniform Disciplinary Act. Id. at 836.
11 Strandburg & Burda, supra note 10, at 488.
pharmaceutical drugs upon delivery. Essentially, manufacturers of pharmaceutical drugs would be able to verify that their drugs are being sent to the proper individuals via fingerprint geometry or retinal scans. The use of biometric technology would also force Internet pharmacies to be upfront about their identity and the location of their business, because without disclosing this information, they would not be able to receive drug supplies from manufacturers.

This comment explores the current methods of Internet regulation at both state and federal levels and presents the need for new stricter regulation on both pharmaceutical manufacturers as well as Internet pharmacies. In addition, this paper addresses new forms of regulation using advanced technology such as RFID, 2D barcodes, and biometrics and establishes how the benefits of these technologies greatly outweigh the drawbacks. Finally, this comment will urge Congress to take further action in implementing legislation that would require Internet pharmacies to utilize this new technology.

II. DIFFERENT TYPES OF INTERNET PHARMACIES

Internet pharmacies operate in many different ways. In most states, online pharmacies that offer prescription and non-prescription drugs are legal. These sites are known as “brick and mortar” online pharmacies because they function much like traditional pharmacies and require a prescription from a physician before an order is processed. These sites permit physicians to send a prescription via fax, phone, or mail and verify the prescription before sending the medication to the patient.

Another type of online pharmacy requires consumers to fill out a questionnaire about the patient’s symptoms, current

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13 See generally Strandburg & Burda, supra note 10, at 495-96; see also Nicolas P. Terry, Prescriptions Sans Frontieres (or How I stopped Worrying about Viagra on the Web but Grew Concerned about the Future of Healthcare Delivery), 4 YALE J. HEALTH POL’Y L. & ETHICS 183, 259 (2004).

14 Strandburg & Burda, supra note 10, at 493-94.

15 Alexander, supra note 1, at 2.

16 Id; see also Egan, supra note 8, at 32.

17 Alexander, supra note 1; see also Yoo, supra note 4, at 63.
medications, and medical history. At these sites, a patient can obtain a prescription without an examination. Once the doctor receives the questionnaire, he or she gives a diagnosis based on the information provided by the patient and prescribes the medication. Depending on the site, the online pharmacy may charge the consumer for the consultation. Some online pharmacies charge the patient for the consultation only if the doctor fills a prescription.

Finally, the last category of online pharmacy is called a “rogue” pharmacy, because it dispenses drugs without a prescription. A rogue pharmacy operates by allowing consumers to purchase drugs after completing an order form without a diagnostic service. This is the most dangerous approach because it allows consumers to self-medicate without any physician contact. One of the greatest problems with these rogue pharmacies is that many operate outside of the U.S. and are beyond the reach of U.S. law governing drug sales.

III. BENEFITS OF INTERNET PHARMACIES

The abundance of benefits derived from purchasing drugs online, such as convenience, privacy, and lower costs, has driven many consumers to regularly use Internet pharmacies for their prescription needs. The convenience of online pharmacies is particularly appealing to the elderly and the chronically ill, who find it difficult to travel to receive their medications. By ordering their

18 Yoo, supra note 4, at 64.
19 Alexander, supra note 1.
20 Id.
21 Yoo, supra note 4, at 64.
22 Id.
23 Id. at 65; see also Alexander, supra note 1.
24 Yoo, supra note 4, at 65; Bussiki & Clifton, supra note 3, at 546.
25 See Yoo, supra note 4, at 65.
26 Id.
28 Yoo, supra note 4, at 61; see also Bussiki & Clifton, supra note 3, at 544.
drugs on the Internet, they can avoid driving the distance to the local pharmacy and having to wait at the counter. In addition, Internet pharmacies allow consumers who have chronic health problems that require frequent medication to place their orders online without constantly having to remember to pick them up. Many Internet pharmacies have automatic refill settings which allow users to register once and automatically have their monthly or weekly prescription shipped to them. Other sites have reminder settings which allow users to receive emails about their upcoming refills.

Many customers are also drawn to Internet pharmacies because of the privacy that they provide. Consumers who have sexually transmitted diseases or erectile dysfunction might feel uncomfortable discussing their concerns with a pharmacist over the counter where others may be within earshot. These customers can use Internet pharmacies to consult with pharmacists about their needs or concerns about a particular medication without feeling embarrassed. Consequently, many Internet pharmacies target consumers who are interested in purchasing erectile dysfunction or HIV medications online.

Finally, one of the main reasons why consumers are drawn to online pharmacies is the lower cost of prescriptions. Internet pharmacies can offer better prices than typical brick and mortar pharmacies because their operating costs are much lower. A 2001

29 Alexander, supra note 1.
30 Id.
31 See, e.g., Walgreens, Most Common Questions Archive, http://www.walgreens.com/help/faq/faqById.jsp?faqId=autorefill.xml (describing the auto refill system which allows prescriptions to be refilled automatically as often as the user selects. The user is then notified by e-mail about when the prescription is processed and when it is ready) (last visited Mar. 12, 2008).
32 See, e.g., drugstore.com, Customer Help, at www.drugstore.com (last visited March 12, 2008)(search under help option "reminder"; then follow "Prescription Reminder E-mail Changes" link).
33 Yoo, supra note 4, at 61.
34 See Alexander, supra note 1.
35 Id.
36 Id.
37 Bussiki & Clifton, supra note 3, at 544.
38 Id.
study by the General Accounting Office found that for several medications, the prescription prices were cheaper at Internet pharmacies than at traditional drugstores. In addition, further savings are available to American customers if they purchase their medications from online pharmacies in Canada and other countries because of the cheaper prices. As a result, the Canadian online Pharmacy industry has made profits of over 800 million annually, much of which comes from American consumers.

IV. STATE REGULATION

One form of regulation of online pharmacies is through state law. Most states have the power to license physicians and pharmacists. In addition, both pharmacists and physicians may practice only in states in which they are licensed. Most states, including Texas, impose strict rules requiring that a physical examination take place before a physician can prescribe using the Internet. Specifically, the Texas State Board of Pharmacy states that an examination conducted by a physician must involve more than an interview over the phone or an electronic consultation. Oklahoma and Kentucky have also implemented statutes that ban physicians from writing online prescriptions without consulting with the patient and conducting a physical examination. Additionally, some states do not even allow out-of-state pharmacies to ship products into their state unless they have “non-resident” licenses.

39 Id.
40 Clifford Krauss, Internet Drug Exporters Feel Pressure in Canada, N.Y. TIMES, Dec. 11, 2004, at A1 (Canada's drug prices are regulated compared to America's unregulated drug prices).
41 Id.
42 Alexander, supra note 1, at 4.
43 Id.
44 Newsletter, supra note 9.
45 Id.
46 Alexander, supra note 1; see also OKLA. STAT. ANN. tit. 59, § 492 (West 2005); KY. REV. STAT. ANN. § 218A.180 (West 2004).
47 See, e.g., TEX. OCC. CODE ANN. § 560.051 (Vernon 2004); FLA. STAT. ANN. § 465.0156(1) (West 1999) ("Any pharmacy which is located outside this state and which ships, mails, or delivers, in any manner, a dispensed medicinal drug into this state shall be registered with the
Many states have imposed harsh penalties on pharmacists and physicians for failing to comply with their regulations and have shut down Internet pharmacy sites for prescribing medications without conducting a medical examination.\textsuperscript{48} Some of the more stringent penalties have involved expensive fines, and even imprisonment, to pharmacists who violate state statutes by dispensing drugs to customers without a valid prescription.\textsuperscript{49} In one Texas case, a pharmacist who was found guilty of selling drugs without a prescription was sentenced to 20 years imprisonment.\textsuperscript{50} States are imposing harsh sentences as a method of deterrence to ensure that pharmacies operating in their jurisdiction abide by their regulations.

Although most states have been quick to amend their pre-existing statutes to include provisions regarding Internet pharmacies, few states have taken actions to implement provisions involving the use of RFID tags to track pharmaceutical drugs. California is an exception in that the California State Board of Pharmacy has a committee researching and developing a scheme to electronically track prescription drugs commencing with their departure from the manufacturer, to their distribution by the wholesaler, and lastly, their reception by the pharmacy.\textsuperscript{51} Essentially, the Business and Professions Code of the California State Board of Pharmacy will require all drug manufacturers and wholesalers doing business within the state to use electronic tracking devices to trace the distribution of prescription drugs.\textsuperscript{52} These requirements are planned

\textsuperscript{48} Ledbetter, \textit{supra} note 27 ("In California, state regulators recently shut down two Web sites – www.drpropecia.com and www.deyarmannmedical.com – run by a San Diego osteopath who was using the Web to prescribe baldness treatments without performing a traditional medical examination."); see also US Says 18 Charged in Illegal Online Pharmacy Case, Reuters, August 2, 2007 at http://www.reuters.com/article/latestNews/idUSN02379048 (detailing a case California in which several pharmacists and physicians were involved in a network which “sold the drugs to customers who lacked prescriptions from a personal physician”).


\textsuperscript{50}\textit{Id}.

\textsuperscript{51} California State Board of Pharmacy, Notice of Meeting and Agenda Enforcement Committee and Work Group on E-Pedigree (Sept. 20, 2007).

\textsuperscript{52} California State Board of Pharmacy, Template for Submissions Regarding Implementation
to go into effect as of January 1, 2009. This proposed regulation will help address foreign Internet pharmacies by requiring them to have RFID tags attached to the drugs that they ship into California. In turn, authorities in California will know where these drugs are coming from and which foreign Internet pharmacies are responsible for distributing them to consumers. In order for this regulation to be successful, it also requires states to have close contact with federal authorities who can consult with the governing bodies in foreign jurisdictions where these “rogue” sites are located. While California is clearly ahead of the other states in this area, this may be the beginning of a trend with other states following suit within the next few years.

V. INDUSTRY SELF REGULATION

In addition to state regulation, there have also been directives from within the pharmaceutical industry including the National Association of Boards of Pharmacy (NABP). In 1999, NABP created the Verified Internet Pharmacy Practice Sites program (VIPPS) in response to public concern about the safety of purchasing drugs off the Internet. In order to be accredited under VIPPS, all pharmacies, including online pharmacies, must abide by the licensing and inspection requirements of the states in which they conduct business. In addition, online pharmacies must demonstrate that they have complied with VIPPS criteria including “patient rights to privacy, authentication and security of prescription orders, adherence...”

Date of California ePedigree Laws (Bus. & Prof. Code § 4163.5).

53 Id. (“Business and Professions Code sections 4034 and 4163 provide that absent further action by the Board of Pharmacy, California electronic pedigree requirements will be effective as of January 1, 2009. Business and Professions Code section 4163.5 vests the Board with authority to extend the date for compliance with these requirements to a new date of January 1, 2011, if the ‘Board determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state.’”).

54 Id.

55 Henkel, supra note 4; see also Verified Internet Pharmacy Practice Sites, VIPPS National Association of Board of Pharmacy, http://vipps.nabp.net/verify.asp [hereinafter NABP].

56 NABP, supra note 54.
to recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.” 57 The VIPPS program is meant to provide consumers with information about online pharmacies and ensure that they are purchasing drugs from legitimate online pharmacies. 58 NABP “does not have the authority to regulate Internet pharmacies,” but those who wish to use the VIPPS accreditation must follow the above criteria. 59 Although the VIPPS program is a useful tool for consumers to identify legitimate Internet pharmacies, given the amount of “rogue” sites, self-regulation is simply not a sufficient form of deterrence. 60

VI. FEDERAL REGULATION

A. Controlled Substances Act and Food and Drug Cosmetic Act

The most stringent regulation involving Internet pharmacies has come from the federal government. The Controlled Substances Act is an example of federal legislation that has been used to regulate online medications by requiring pharmacists to have a valid prescription from a physician before dispensing prescription drugs (as determined under the Federal Food, Drug and Cosmetic Act) to patients. 61 Furthermore, this Act subjects both pharmacists and physicians to penalties for failure to issue a prescription with “a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice”. 62 The Act is used to focus

57 Id.

58 Henkel, supra note 4 (quoting Kevin Kinkade, NABP executive committee chairman, who stated “VIPPS will be of tremendous benefit to consumers who need to be certain that the prescription medications they receive are from legitimate online pharmacies”).

59 Alexander, supra note 1, at 6.

60 See id.


62 21 C.F.R. § 1306.04 (a) (2004) (“The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription”).
on the tendency of many Internet pharmacies to issue a prescription without a consultation and therefore is used to enforce these sites to require a formal physician-patient relationship before the patient can be given a valid prescription.63

Although the Controlled Substances Act as well as the Food Drug and Cosmetic act may require a prescription before a patient may obtain drugs, this is difficult to enforce given the fact that “rogue” Internet pharmacies are located all over the world.64 Essentially, this legislation is limited to the regulation of online pharmacies located within the United States. Another regulatory issue with this legislation is that rogue sites can be difficult to track and monitor given the complex nature in which they are set up, usually with multiple links.65 Therefore, new legislation must be geared towards tracking international online pharmacies that import drugs into the United States. It is not sufficient to pass legislation requiring valid prescriptions because the new legislation would be difficult to enforce given that new sites can be created and old sites can be removed quickly with little effort.66

B. Safe Internet Pharmacy Act of 2007 and Ryan Haight Online Pharmacy Consumer Act of 2007

Some of the drawbacks of the Federal Food, Drug and Cosmetic Act have been addressed by a new bill entitled the Safe Internet Pharmacy Act of 2007, which proposes to amend the aforementioned Act to specifically provide for the regulation of online pharmacies.67 A similar statute entitled Ryan Haight Online Pharmacy Consumer Act of 2007 proposes an analogous amendment to the Controlled Substances Act.68 Both Acts require Internet

63 Alexander, supra note 1, at 5.
65 Alexander, supra note 1.
66 Id.
68 Online Pharmacy Consumer Act of 2007, S. 980, 110th Cong. (2007) (amending the Controlled Substances Act to require Internet pharmacies to place the following statement
pharmacies to offer interactive and meaningful consultation by a licensed pharmacist to the patient as well as to verify the validity of prescriptions by direct communication. However, the Safe Internet Pharmacy Act contains a section that is markedly different from the Controlled Substance Act and the Federal Food, Drug and Cosmetic Act in that it directs the Board of Governors of the Federal Reserve System to establish procedures that are designed to prevent the introduction or completion of restricted transactions with unlicensed pharmacies to a designated payment system. This is a novel regulation that has not been addressed by other statutes. The benefit of this regulation is that it might be easier to identify the owners of Internet pharmacies and their location by tracking payments.

The Safe Internet Pharmacy Act also has a section directed specifically to Internet pharmacies located outside the United States and requires pharmacies wishing to conduct business within the United States to follow certain regulations. Some of these requirements include providing an agent for service of process in the United States, agreeing to be subject to the jurisdiction of the United States, and placing markings on the shipments including anticounterfeiting and track and trace technology. This is one of the first pieces of Federal Legislation that has addressed the jurisdictional as well as tracking problems created by foreign internet pharmacies shipping drugs into the United States. Not only does this regulation require that these sites register an agent for service that makes them more accessible, but it also addresses the use of track and trace technology that aids authorities in locating these foreign sites.

on their website as a way of letting consumers and authorities know it is a legitimate website: “This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner, which includes at least one prior in-person medical evaluation.” This online pharmacy complies with section 309(e) of the Controlled Substances Act (21 U.S.C. § 829(e)).

69 Id.; see also S. 596, supra note 67.
70 See id..
71 Id.
72 Id. ("conditioning that in the case of an Internet Pharmacy whose principal place of business is located outside the United States, verification... that the Internet Pharmacy agrees to affix to each shipping container of drugs to be shipped in the United States such markings as the Secretary determines to be necessary to identify that the shipment is from a licensed internet pharmacy, which may include anticounterfeiting or track-and-trace technologies.

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The Online Pharmacy Consumer Protection Act also addresses foreign Internet pharmacies. However, it proposes that after the adoption of the Act, an annual report concerning the actions taken by the Drug Enforcement Agency to combat foreign Internet pharmacies dispensing controlled substances without a subscription be submitted to Congress. Specifically, the report must include the efforts of the Drug Enforcement Administration to work with domestic and multinational pharmaceutical companies and others to build international cooperation and a commitment to fight on a global scale the problem of distribution of controlled substances over the Internet without a valid prescription. Although this Act does not address the use of track and trace technology to locate foreign internet pharmacies, it does promote the collaboration of drug enforcement authorities with local, as well as foreign companies, to address the problems of the security of America’s drug supply. It is important to note that without the assistance of international pharmaceutical companies and foreign governing bodies, regulating the conduct of the “rogue” sites within the United States would be impossible.

C. Reducing Fraudulent and Imitation Drugs Act of 2007

By far the most radical and innovative bill, the Reducing Fraudulent and Imitation Drugs Act of 2007 proposes to regulate Internet pharmacies in a very different way by using Radio Frequency Identification. The main purpose of this legislation is to direct the Secretary of Health and Human Services to require the incorporation of counterfeit-resistant technologies into the packaging of prescription drugs. To achieve this end, the Act would require the use of radio frequency tagging technology or other tracking technologies, such as 2D serialized barcodes, which could be included within the meaning of the statute. Second, the Act would

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74 Id.
76 Id.
77 Id. ("The Secretary of Health and Human Services shall require the packaging of any prescription drug incorporate ... radio frequency identification (RFID) tagging technology, or similar trace and track technologies that have an equivalent function.").
use the tracking technology towards 1) implementing inventory control, 2) tracking and tracing a prescription drug as it travels through the supply chain, and 3) verifying shipment and receipt. Therefore, under the Act, manufacturers and distributors of prescription drugs are compelled to incorporate the use of these tracking devices.

As its name suggests, the original purpose of the statute is to prevent the distribution of counterfeit drugs. However, the tracking technology is also useful towards uncovering the identity and location of “rogue” internet pharmacies whose anonymity is of great concern to government agencies and the legislature. Although the Act does not specifically address foreign internet pharmacies it does state, “[t]he Secretary of Health and Human Services shall require that the packaging of any prescription drug incorporate . . . radio frequency identification (RFID) tagging technology, or similar trace and track technologies that have an equivalent function.” Presumably, this technology must be placed on “any” drug entering the United States. This interpretation is the only sensible one given the fact that the purpose of this statute would be greatly thwarted without inferring that this Act applies to all drugs infiltrating the U.S. supply chain.

This Act may be critiqued as breaching the privacy concerns of consumers; however, this should not be a concern because it safeguards the identity of the end prescription drug consumer who orders the drug from the site. The purpose of the statute is only to identify where the drugs are coming from and not the identity of the

78 Id.
79 Id.
80 Id. (The purpose of the bill is “to direct [the] Secretary of Health and Human Services to require the incorporation of counterfeit-resistant technologies into the packaging of prescription drugs, and for other purposes.”).
81 See A Prescription for Safety: The Need for H.R. 3880, The Internet Pharmacy Consumer Protection Act, Hearing on H.R. 3880 Before the H. Comm. on Gov’t Reform, 108th Cong. (2004) (noting Internet sites can be difficult to track given their “broad reach, relative anonymity, and ease of creating new or removing old websites.”).
82 Id.
83 Reducing Fraudulent and Imitation Drugs Act of 2007, H.R. 2716, 110th Cong. (2007). (“The Secretary shall prohibit technologies ... from containing or transmitting any information that may be used to identify a health care practitioner or the prescription drug consumer.”).
customers ordering from these sites. One of the things that this Act does differently from the ones described above is that it holds pharmaceutical manufacturers and distributors liable for tracking their drugs.\footnote{Id.} Past legislation has placed a great burden on both governmental agency resources and physicians in identifying and hunting down “rogue” sites. Accordingly, this shift may signal the beginning of a trend in legislation towards placing the responsibility on pharmaceutical manufacturers to trace the whereabouts of their drugs. The Reducing Fraudulent and Imitation Drugs Act of 2007 is currently the only piece of federal legislation that proposes the use of RFID tags to track prescription drugs. Although the Safe Internet Pharmacy Act discussed above requires foreign internet pharmacies to use track and trace technology, it does not specify which technology is sufficient to meet the requirement under the statute. Hopefully, lawmakers are realizing that the statutes which require a physician-patient relationship have not been effective in controlling “rogue” internet pharmacies, as their increased proliferation evinces the futility of current legislation.\footnote{Id.}

\section*{D. United States Food and Drug Administration RFID Workgroup}

The United States Food and Drug Administration (FDA) has shown an interest in using tracking technology as a means to prevent the circulation of counterfeit medication from “rogue” internet pharmacies.\footnote{U.S. Food and Drug Administration, \textit{supra} note 63.} The FDA has submitted a report stating that track and trace technology is needed to “secure the integrity of the supply chain.”\footnote{Id.} Specifically, the FDA promoted the use of RFID since it found this technology to be the most useful for tracking drugs through every step of the supply chain.\footnote{Id. ("We particularly advocated for the implementation of electronic track and trace mechanisms and noted that radio-frequency identification (RFID) is the most promising...".)} An “RFID workgroup” was...
created to monitor the adoption of RFID technology by pharmaceutical companies and examine its effectiveness. The FDA has acknowledged that new measures need to be implemented to combat the distribution of counterfeit drugs—especially those sold by rogue internet sites.

V. RFID AND 2D BARCODES OVERVIEW

RFID uses radio waves to identify objects from information embedded in RFID tags. RFID tags consist of two parts: 1) memory that holds identifying information such as a number and 2) an antenna that sends out a radio frequency to an apparatus, which then reads the identifying information embedded in the tag. Pharmaceutical companies can place information in the tag regarding both the nature of the drugs in the package, as well as “the distribution history of the package, including its final destination,” to track the drug through every stage of the distribution chain. A major benefit of this technology is that the information about the drug can be updated every time the drug is placed in new hands by any person having the right or access to the RFID database. Moreover, multiple RFID tags can be read simultaneously by strategically placing a reader to scan the products obviating the need for humans to scan each individually. This helps the efficiency of the distribution process because large numbers of RFID tagged drugs

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89 Id. ([The internal cross-agency] group is charged to monitor adoption of RFID in the pharmaceutical supply chain, pro-actively identify regulatory issues raised by the use of this new technology, and develop straightforward processes for handling those issues.].)

90 Id. ("Although we continue to believe that the U.S. drug supply is among the safest in the world, more work needs to be done to further implement these measures and further secure our nation’s drug supply.").


92 Id. at 3-4.

93 Id. at 4.


95 Id.
can be read and monitored quickly.96

In addition to RFID, 2D barcodes can also track and trace pharmaceutical drugs.97 A barcode encodes information using the widths and heights of the bars and spaces of the barcode.98 Although barcodes come in both one-dimensional (1D) and two-dimensional (2D) formats, 2D barcodes are capable of holding more information.99 These barcodes can store information about the type of drug, location of the drug, and final destination of the drug.100 However, whereas radio frequency tags can be updated continuously, barcodes are read-only. Accordingly, as the drug continues down the supply chain, information about the location of the barcode cannot be updated.101 Moreover, large inventories of pharmaceutical drugs cannot be read without human intervention as they can be with RFID tags.102 Each coded unit must be individually scanned at each step of the supply chain.103 Overall, barcodes are not as effective as RFID tags, because they do not track the drug as it changes possession.104 Nevertheless, barcodes are a preferred alternative to not having any tracking system.

96 Id.
99 Ghosh, supra note 93, at 597.
100 Giacalone, supra note 10, at 71 (noting that 2D barcodes can hold "hundreds of characters in a very compressed area...[and] can contain information specific for that particular drug product, such as a unique serial number per drug unit, a manufacturer's lot number, expiration dating for the product and the FDA's National Drug Code (NDC) number.").
101 Ghosh, supra note 93, at 597.
102 Id.
103 Giacalone, supra note 10, at 71.
104 Ghosh, supra note 93, at 597 ("Each time a drug changes hands, the barcode cannot be updated with information to indicate that the drug has been sold to a new wholesaler. In this way, barcodes do not track the chain of custody of a drug.").
A. Advantages and Disadvantages of Implementing RFID and 2D Barcode Technology

RFID technology is the most promising technology to prevent counterfeiting by online pharmacies (through inventory control and tracking information) as well as to identify rogue internet pharmacies that in the past have been protected by their anonymity (by requiring disclosure of the identity and location of these pharmacies). However, there are several limitations to using RFID technology. One such limitation is the cost and expense of implementing the technology to all pharmaceutical drugs of a company.105 The cost of using RFID tags is approximately thirty cents per bottle, whereas the cost of using barcodes is one cent per bottle.106 According to some analysts, the cost to large-scale manufacturers to implement RFID technology into their entire enterprise could range from nine million to twenty-five million.107

Many pharmaceutical companies have acknowledged the high cost of using RFID technology and have created pilot studies using RFID tags on certain prescriptions rather than on all the drugs the company offers.108 One of these companies is Pfizer, which created a pilot program to tag every unit of Viagra sold in the United States.109 Pfizer has found that RFID technology can save their company billions of dollars by preventing the distribution of counterfeit drugs as well as creating more efficient inventory control.110 Pfizer has been very pleased with the success of the RFID Viagra Pilot and now plans to expand the use of RFID tags to other prescription drugs it offers.

105 Giacalone, supra note 10, at 73.
107 Ghosh, supra note 93, at 593-94.
109 Id.
110 Ghosh, supra note 93, at 594 (by using RFID track and trace technology, pharmaceutical companies can know exactly where their drugs are going).
such as Celebrex.111

Although the costs associated with implementing RFID technology are high, the costs will decrease as more pharmaceutical companies begin using this technology.112 Pfizer is not the only pharmaceutical company that has decided to implement this technology; West Pharmaceutical Services has decided to place RFID tags on its drugs as well.113 Therefore, as more pharmaceutical companies employ RFID tags to protect their drugs and consumers, it is likely that the increased demand for technology will drive prices down.

Another obstacle of RFID technology is that each entity of the supply chain—including the manufacturers, distributors, and pharmacists—must use the same standard in order for the technology to be efficient.114 It is essential that there be a uniform system not only in the United States but all over the world in order to ensure the safety of the supply chain.115 Groups within the European Union have shown an interest in the security of pharmaceutical drugs as well as online pharmacies and have recommended the use of RFID technology.116 However, since many American pharmaceutical companies do business abroad, and vice versa, it is crucial that these companies and lawmakers get together with countries around the world to develop a standardized track and trace system.117 Many critics will argue that creating a working uniform RFID system is too burdensome and expensive. However, Tim Marsh, the Senior

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111 Pfizer Manager Discusses the Viagra RFID Pilot, RFID UPDATE, June 12, 2007, http://www.rfidupdate.com/articles/index.php?id=1374 [hereinafter Pfizer Manager] (“The company aims to have all cases sold in the U.S. of the popular arthritis pain reliever Celebrex tagged by the end of this year.”).
112 Ghosh, supra note 93, at 595.
115 Id. at 502.
116 Moore, supra note 96 (the Board of European Federation of Pharmaceutical Industries and Associations has recommended the use of track and trace technology as a means to halt counterfeiting).
117 See generally id.
Manager of Pfizer Global Package Technology in charge of the Pfizer Viagra Pilot study, has stated that the use of this technology has been a success, despite requiring much experimentation and tweaking.\textsuperscript{118} As he stated, “The success of this project is our learning how to deploy the technology as a pharmaceutical packager in a way that is scalable. We understand what is scalable and what’s not, what’s mature, and how to make it work beyond our door.”\textsuperscript{119} The use of this technology will take some experimentation and work on the part of pharmaceutical companies, but it is obvious that the rewards outweigh the costs. In addition, it is important to note that with increased demand, it is likely that RFID companies will begin to develop more advanced technology tailored to the needs of pharmaceutical companies.\textsuperscript{120} This is conceivable given the fact that the market for this technology is enormous since there are approximately ten billion units of drugs shipped each year from manufacturers to pharmacies and doctors in the United States as well as Europe.\textsuperscript{121}

2D barcodes also face similar limitations to those discussed above in relation to RFID technology. In order to be efficient, pharmaceutical companies, distributors, and pharmacies using 2D barcodes must all have the same “data standard.”\textsuperscript{122} If there is no uniformity in regards to which barcodes are being utilized then the use of barcodes becomes expensive and futile.\textsuperscript{123} 2D barcodes also suffer from serious drawbacks that do not affect RFID technology. For example, the efficiency of track and trace technology is hindered by the fact that 2D barcodes are read-only and cannot be updated.\textsuperscript{124} It is extremely beneficial to pharmaceutical companies to know that their drugs are being shipped to the proper entities. As previously discussed, one of the problems with rogue internet pharmacies is that

\textsuperscript{118} Pfizer Manager, supra note 107.  
\textsuperscript{119} Id.  
\textsuperscript{120} See id. (hoping that the success of its pilot study will result in others implementing RFID technology).  
\textsuperscript{122} Liang, supra note 108, at 501.  
\textsuperscript{123} Id.  
\textsuperscript{124} Ghosh, supra note 93, at 597.
their anonymity makes them difficult to locate, and without the ability to update the final destination of the drug, this issue is not resolved. Another reason that 2D barcodes are not as effective as RFID tags is that they require physical scanning of each item, which thwarts the efficiency of the supply chain process thereby causing great expense to those large manufacturers who have millions of sales units that need to be scanned. 2D barcodes may be less expensive, but manufacturers do not derive as many benefits from this technology as they do from RFID tags.

VI. BIOMETRICS OVERVIEW

Biometrics is the use of physical characteristics for identification or verification of identity purposes. Biometric technology creates an individual’s biometric identifier, such as a fingerprint or retina scan, records it in a database, and when an individual seeks later identification, their biometric information is compared with that on file. The most common form of biometric identification is the fingerprint. Biometric technology can play a vital role in the fight against rogue internet pharmacies by requiring those pharmacies to verify their identity when making electronic payments with pharmaceutical manufacturers. For example, when an executive of an internet pharmacy purchases drugs from a pharmaceutical manufacturer, he would have to use a fingerprint scan to verify his identity.
identity and bank account information such as his name and address. The notion of “following the money” is not a novel idea and has in fact been proposed as a solution to regulating internet pharmacies by many researchers. However, one of the problems with internet pharmacies is their anonymity. Combining financial transactions with biometric technology would require these rogue sites to disclose their identity before purchasing drugs from manufacturers. Some pharmacy chains have implemented biometric technology in the form of a “Pay by Touch” system. The “Pay by Touch” uses “a secure finger scan to debit a shopper’s checking account just like using a check or debit card.” Thus far, this technology has only been used at grocery store pharmacies and has not been applied to internet pharmacies. However, if these grocery store pharmacies are using this technology successfully as a method of patient safety by verifying the identity of consumers (by authenticating that the same person that was prescribed the medication is picking it up and paying for it), then internet pharmacies should not be permitted to have lower safety measures. In fact, there is a much greater security concern about internet pharmacies dispensing drugs without a prescription than customers attempting to pick up drugs using a false identity at the local drugstore.

Another way to use biometrics to regulate internet pharmacies is by requiring a fingerprint scan upon delivery of the drugs. Once

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133 Id.

134 See generally Cole, supra note 130 (describing pharmaceutical companies’ plans to
again, this can help with disclosing the identity of those who operate internet pharmacies. It has been proposed that shipping companies, such as FedEx and UPS, should be required to provide tracking information about the destination of pharmaceutical shipments to internet pharmacies. However, for shipping companies that send millions of packages a day, it does not seem feasible to provide tracking information for every company and shipment they process. Consequently, requiring a fingerprint scan when the drugs are delivered could be an alternative way to require disclosure of the identity and location of the purchaser of the drugs. The combination of biometric technology for the payment and delivery of drugs would make it difficult for internet pharmacies to falsify information.

A. Advantages and Disadvantage of Implementing Biometric Technology

One of the main concerns involving the use of biometric technology is the privacy to the consumer and the internet pharmaceutical companies. However, much like the “Pay by Touch” system, when performing monetary transactions the account information would not be exposed, making this system even safer than shopping at a grocery store where employees may be exposed to account numbers. In addition, biometric technology provides much more security than passwords, which can easily be stolen or guessed. Many of these privacy concerns are currently unfounded since biometric technology is being used for commercial purposes, such as access to ATMs and health clubs; health purposes, such as access to electronic medical records; and even government purposes, such as passport control, driver’s licenses and criminal

electronically track their drugs through the distributions system).

135 Id. (“Both FedEx and UPS continue to support DEA investigations with tracking information on origin and destination of shipments.”).

136 Id. (quoting UPS spokeswoman Susan Rosenberg who stated, “With 13.5 million packages a day it’s not practical.”).

137 See Strandburg & Burda, supra note 10, at 495 (discussing concerns with privacy invasive surveillance, loss of anonymity, and fear of biometric identity theft).

138 PR Newswire, supra note 131 (“Finger scans are more secure than paper checks or debit cards because the account numbers are not exposed to anyone—not even to the store associate.”).

Most of the concern regarding privacy is that the biometric data can be easily stolen or replicated by identity thieves. First, there is a concern that the databases that contain the biometric information of pharmaceutical consumers could easily be accessed and the information abused. However, it is likely that the access to the database would be strictly limited and even have a backup biometric security system requiring users to identify themselves before accessing the database. For example, biometric security has been proposed to regulate access to electronic health records and patient medical information.

Second, there is a privacy concern that biometric identifiers could be easily replicated. However, Americans currently live in an age where many commercial transactions, such as banking, are performed online in which the only barrier to access is a password which can easily be guessed or, if forgotten, sent to an e-mail address that could already be compromised. Replicating a 7-digit password is much easier than replicating a fingerprint or an iris scan. Doctor Stephanie Schuckers, an electrical and computer engineering professor who has been researching biometrics, addressed the issue of replication in a recent New York Times interview stating, “it

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140 Id.; see also Strandburg & Burda, supra note 10, at 494 ("Current and prospective public sector applications of biometric technologies include surveillance, criminal identification, identification for government benefit distribution, voter identification, passports, visas, border control, driver’s licenses.").

141 Strandburg & Burda, supra note 10, at 495.

142 See generally John D. Woodward, Biometric Scanning, Law & Policy: Identifying the Concerns-Drafting the Biometric Blueprint, 59 U. Pitt. L. Rev. 97 (1997) (discussing efforts to secure biometric data in order to prevent misuse).


144 Id. ("For example, biometrics can be effectively used to limit access to a patient’s medical information stored on a computer database.").


146 Id. ("From an administrator’s perspective, if such a system is correctly implemented, the likelihood of a malicious impostor successfully replicating or otherwise circumventing another user’s biometric is miniscule when compared to the likelihood of guessing a password.").
would take determined handiwork to pull off such a fraud." Dr. Schuckers acknowledged that there are some flaws in biometric security, and she is currently developing new technology that will detect a finger’s pore perspiration patterns as a method of decreasing the likelihood of fingerprint replication. This technology functions with fingerprint sensors detecting the moisture changes on the ridges of the skin and distinguishing between a real finger as opposed to a cadaver or a replicated finger using a mold such as gelatin. The reality is that no technology is perfectly secure; however, as more biometric technology is developed and tested, it is improved. The benefits of tracking drug supply and delivery, and forcing internet pharmacies to disclose their identity and location, greatly outweigh the unsubstantiated fear of a breach of privacy.

VII. CONCLUSION

The problem of "rogue" internet pharmacies and securing the American drug supply has been addressed by legislation at both the state and federal levels, as well as by the pharmaceutical industry itself. However, the current legislation in place has been ineffective in regulating these pharmacies, due in large part to the fact that many of these sites are located outside the United States, and are therefore able to retain their anonymity. Congress must take more action to prevent the drugs from these pharmacies, many of which are counterfeit, from entering the United States pharmaceutical supply chain. In order to accomplish this goal, United States lawmakers must be persistent in requiring pharmaceutical companies to adopt tracking technology to trace their drugs as they progress through the supply chain. In addition, more legislation must be passed focusing


148 Id.

149 Stephanie A.C. Schuckers et al., Comparison of Classification Methods for Time-Series Detection of Perspiration as a Liveness Test in Fingerprint Devices, in Biometric Authentication 256, 258 (David Zhang & Anil K. Jain eds., 2004).
on foreign “rogue” pharmacies that have infiltrated the American market. Until Congress decides to hold pharmaceutical companies liable for their drug distribution, as well as address the increasing supply of foreign drugs being shipped into the United States, there will be considerable concerns about the integrity of the national drug supply.