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Progress in the Challenge to Regulate Online Pharmacies

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PROGRESS IN THE CHALLENGE TO REGULATE ONLINE PHARMACIES

JEFF KARBERG

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I. INTRODUCTION

Imagine for a moment that after borrowing a credit card, a teenager strolls down the block to the local pharmacy. At the pharmacy, a doctor is at the door waiting and willing to prescribe anything to anyone. After answering a few questions, the teenager receives his prescription, where he takes it to the drug counter and places an order for a dangerous amount of painkillers. Imagine further that the teenager develops an addiction to the drugs and purchases an increased dosage each visit until finally, the teen dies from an overdose from the easily obtained prescription drugs.

The situation described above is drawn from a real event.¹ Nearly the very same chain of events happened to seventeen year old Ryan Haight. The only difference was that Ryan never even had to leave his home. Ryan visited an online pharmacy and obtained a prescription from a doctor he had never met for drugs he did not need. Using his father's credit card, Ryan had the drugs delivered to his home.² Tragically, Ryan became addicted to the drugs and eventually died of an overdose at age eighteen.³

Ryan's tragic story was preventable. There are ample barriers and regulations in place that would have prevented Ryan's death if he had tried to obtain the drugs at his local pharmacy rather than one he found online.⁴ The need for the government to regulate online pharmacies is well documented,⁵ yet the federal government has largely avoided any meaningful regulation until passing the Ryan Haight Online Pharmacy Consumer Protection Act in October of 2008.⁶

The transition from brick and mortar storefronts into cyberspace has presented both opportunities and challenges. This is especially true for online pharmacies, where medicine and technology come together in a relatively new way. Online pharmacies present a unique challenge by creating a tension between providing inexpensive remote health care and the safety of in person health care.

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 is the first federal bill passed specifically to regulate online pharmacies. In this note, I will identify the strengths and weaknesses of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the "Ryan Haight Act" or the "Act") and make suggestions for future online pharmacy legislation.

Part II of this note provides background information about online pharmacies. Part III discusses the agencies responsible for online pharmacy regulation and explains existing federal regulation. In explaining the existing online pharmacy regulation, Part III of this note also identifies the strengths and weaknesses of the federal regulation. Part IV provides suggestions for future online pharmacy legislation. Part V of the note is a short explanation of how online pharmacies will be successfully regulated through federal registration. This note concludes that the

¹ Ryan's Cause, <http://www.ryanscause.org> (last visited April 15, 2010). Ryan began using the drugs when he was seventeen years old. Ryan's parents, both of whom worked in the medical field, were shocked to discover that the highly regulated drugs they work with every day were so easily obtained. Since 2001, Ryan's friends and family have worked to further the cause of online pharmacy regulation. *Id.*

² *Id.*

³ *Id.*

⁴ *United States v. Fuchs*, 467 F.3d 889, 899 (5th Cir. 2006) ("Section 841(a)(1) makes it 'unlawful for any person knowingly or intentionally. . . to manufacture, distribute, or dispense . . . a controlled substance.'" (quoting *United States v. Moore*, 423 U.S. 122, 124 (1975))).

⁵ See generally Phil Ayers, Prescribing a Cure for Online Pharmacies, 72 TENN. L. REV. 949 (2005); 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); Kristin Yoo, Self-Prescribing Medication: Regulating Prescription Drug Sales on the Internet, 20 J. MARSHALL J. COMPUTER & INFO. L. 57 (2001).

⁶ 110 P.L. 425 (Oct. 15, 2008).

current federal regulation of online pharmacies provides much needed progress but must be improved to ensure adequate protection.

II. TYPES OF ONLINE PHARMACIES

Generally speaking, “[o]nline pharmacies are divided into three broad categories: traditional online pharmacy, prescribing-based site pharmacy, and rogue pharmacy.”⁷ The traditional pharmacies are little more than an online extension of brick and mortar pharmacies.⁸ Often, this type of pharmacy is a nationally known or recognized chain. Traditional online pharmacies require a prescription before an order for medicine will be filled or delivered.⁹

Traditional online pharmacies place value on consumer protection and have self-imposed standards that are commonly more protective than the regulations the Ryan Haight Act will put in place. CVS and Walgreens provide two well-known examples of traditional pharmacies. Traditional online pharmacies place value on consumer protection and have self-imposed standards that are more commonly more protective than the regulation that what the Ryan Haight Act will put in place. The National Association of Boards of Pharmacy, a non-government association that rates online pharmacies, developed the Verified Internet Pharmacy Practice Sites (VIPPS).¹⁰ The VIPPS program was developed “[i]n response to public concern of the safety of pharmacy practices on the Internet.”¹¹ Eligible online pharmacies display a seal prominently on the front page of their site after VIPPS accreditation.¹² To earn VIPPS accreditation, a pharmacy must “comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals.”¹³ Furthermore, the pharmacies must 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.”¹⁴ Many of the VIPPS requirements go above and beyond the Ryan Haight Act’s requirements for online pharmacies.

⁷ 20 J. Contemp. Health L. & Pol’y 541 at 546.

⁸ *Id.*

⁹ *Id.*

¹⁰ Verified Internet Pharmacy Practice Sites (VIPPS) – The National Association of Boards of Pharmacy, <http://vipps.nabp.net/verify.asp> (last visited Feb. 12, 2009). The VIPPS program was created by the National Association of Boards of Pharmacy (NABP). The NABP was established over 100 years ago to “assist state licensing boards in developing, implementing, and enforcing uniform standards to protect the Public Health.” The NABP has member boards from every state. Canada and Australia are also represented in the association. Internet consumers may check online pharmacies for VIPPS accreditation by simply entering the website URL in a site-checker. *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

A second category of online pharmacy, prescribing-based, is a remote consultation pharmacy.¹⁵ This type of pharmacy will often provide both the prescription and the medication.¹⁶ A customer obtains a prescription after filling out a short questionnaire that is subsequently reviewed by a doctor for approval.¹⁷ Because the doctors are often affiliated with the pharmacy site, most of the prescriptions are approved.¹⁸ Remote consultation pharmacies will be most affected by the Ryan Haight Act.¹⁹

To some, remote consultation pharmacies are a legal gray area.²⁰ Under good faith operation, these pharmacies potentially offer consumers the most convenience, privacy, and savings.²¹ A well-informed consumer would be able to address all of his or her pharmacy needs through one stop shopping. The problems associated with remote consultation pharmacies are potentially deadly when any of the parties involved act with malicious, negligent or improper motives. For example, the consumer may be self-diagnosing a serious medical problem incorrectly or may fill out the online questionnaire dishonestly. Or perhaps the doctor, who is often paid for each prescription dispensed, over-prescribes the patients so that he or she may make more money. Worse yet, the entire website may be a sham pharmacy designed simply to sell pills to addicts. The Ryan Haight Act will address many of these

¹⁵ *Ancier v. Dep't of Health, Med. Quality Assurance Comm'n*, 140 Wn. App. 564, 568 (Wash. Ct. App. 2007). "Applicants must attest they have undergone recent physical examinations, will schedule routine physicals for the duration of the prescription, and will consult local physicians or pharmacists about any adverse reactions or complications." *Id.*

¹⁶ Trust-Meds.com, <http://www.trust-meds.com/faq.php#q12>, (last visited Feb. 16, 2009); Best E-Pharm.com, <http://www.bestepharm.com/faq.php?cat=faq#200> (last visited Feb. 16, 2009). The above websites are examples of remote consultation pharmacies that were operational at the time of submission.

¹⁷ *See Ancier*, supra note 15. Consumers obtained prescriptions by filling out a relatively simple questionnaire. The questionnaire is then reviewed by a doctor. In *Ancier*, the doctor reviewed some 200,000 requests and issued 180,000 prescriptions in a three year period. The doctor did not physically examine any of the consumers receiving prescriptions. Some consumers described their medical conditions as "Need [medication]." *Id.*

¹⁸ *Id.* "Between 2001 and 2004, [the doctor] reviewed approximately 200,000 requests and issued 180,000 prescriptions. [The doctor] did not physically examine or personally interview any of the persons receiving the prescriptions." *Id.*

¹⁹ *See generally* Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 110 P.L. 425 (Oct. 15, 2008).

²⁰ Donald Cooley, InternetDrugLaw.com, <http://internetdruglaw.com/topics/ryan-haight-act/> (Last visited Feb. 12, 2009). (Donald R. Cooley is a criminal defense attorney who posts recent developments concerning internet drug laws on his blog. In many of his posts, Cooley argues that online pharmacies were legal before the Ryan Haight Act was signed into legislation.).

²¹ PharmacyChecker.com: About Online Pharmacies, <http://www.pharmacychecker.com/abouttop.asp> (last visited Mar. 24 2009). The benefits of remote consultation pharmacies include lower prices, privacy, greater access to generic products, convenience, and medical information. *Id.*

concerns in an attempt to clarify the government's stance on the legality of remote consultation pharmacies.²²

A third online pharmacy category is the "rogue pharmacy."²³ The defining characteristic of a rogue pharmacy is that medication is dispensed without a prescription.²⁴ Rogue pharmacies are considered extremely dangerous and are currently illegal.²⁵ Many of them operate from outside of the United States.²⁶ Rogue pharmacy customers are often the targets of fraud and counterfeit medicine.²⁷ There is little difference between this type of pharmacy and back alley drug dealers.²⁸

Although rogue pharmacies are a threat to the safety of internet pharmacy consumers, the government's stance on them is clear. When the government becomes aware of rogue pharmacies, they are shut down and the operators are prosecuted.²⁹ The Ryan Haight Act may have some effect on rogue pharmacies, particularly through the amendment that will increase the length of prison sentences for convicted parties.³⁰ However, the Ryan Haight Act will not substantively change the way consumer, the government, and rogue online pharmacies interact.³¹

²² Government Technology, <http://www.govtech.com/gt/419355> (last visited Mar. 24, 2009). "Rather than try to block all online pharmaceutical sales, the Ryan Haight Act will put online pharmaceutical sales on an equal regulatory footing with those sales through a brick-and-mortar facility." *Id.*

²³ Ayres, *supra* note 5, at 954.

²⁴ 5 Star Pharma, <http://www.fivestarpharma.com/> (last visited Feb. 16, 2009). 5 Star Pharma is an example of a rogue pharmacy website that was operational at the time of article submission. The website is based outside of the United States and purports to mail controlled substances without a prescription. *Id.*

²⁵ Online rogue pharmacies still booming, MSNBC.Com, <http://www.msnbc.msn.com/id/20409515/> (last visited Mar. 24, 2009). Rogue pharmacies often approach retired or in debt doctors and offer them an opportunity to review prescription questionnaires. Doctors are generally paid about 20 dollars for each prescription. The prescriptions are then sent to pharmacies willing to fill them. *Id.*

²⁶ Dispensing and Purchasing Controlled Substances over the Internet, 66 Fed. Reg. 82, 21181, 82 21184 (Apr. 27, 2001) (notice as to application of current laws related to dispensing, purchasing, or importing controlled substances). Rogue online pharmacies are particularly dangerous because they often intentionally mislead consumers. The DEA warns that "[t]hese sites often advise that there have been changes to the U.S. law that authorize the customer to import a controlled substance into the United States without benefit of a prescription." Dispensing and Purchasing Controlled Substances over the Internet.

²⁷ Food and Drug Administration, Counterfeit Drugs Questions and Answers, <http://www.fda.gov/oc/initiatives/counterfeit/qa.html> (last visited Dec. 2, 2008). The Food and Drug Administration (FDA) credits the strong regulatory framework of the United States for low occurrence of counterfeit medicine. Consumers who purchase drugs from foreign entities are therefore more likely to receive counterfeit drugs. A counterfeit drug is a drug sold under an improper name. Counterfeit drugs may contain dangerous incorrect ingredients that may have deadly side effects. *Id.*

²⁸ See Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 26.

²⁹ *Id.*

³⁰ See 21 U.S.C. § 841 et seq. "[I]n the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 10 years and if

III. EXISTING LEGISLATION

A. *About the Regulatory Agencies*

Online pharmacies face federal regulation primarily from the United States Food and Drug Administration (FDA) and the United States Drug Enforcement Administration (DEA).³² Currently, the FDA regulates online pharmacies through the Federal Food, Drug, and Cosmetic Act (FD&C).³³ The DEA regulates online pharmacies through the Controlled Substances Act of 1974.³⁴ The agencies regulate different aspects of online pharmacies. The FDA tends to regulate non-controlled substances while the DEA regulates controlled substances. The two agencies often work together; for example, the “FDA assists DEA in deciding how stringent DEA controls should be on drugs that are medically accepted but that have a strong potential for abuse.”³⁵

According to its mission statement, the FDA is “is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.”³⁶ The FDA officially came into existence after the

death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 15 years” *Id.*

³¹ See generally Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 26. In the eyes of the federal government and the DEA, rogue pharmacies have always been considered illegal and a danger to consumer health. *Id.*

³² What FDA Doesn’t Regulate, <http://www.fda.gov/AboutFDA/WhatWeDo/WhatFDADoesntRegulate/default.htm> (last visited Apr. 12, 2010). The DEA also “establishes limits on the amount of [prescription drugs that have a strong potential for abuse] that are permitted to be manufactured each year.” *Id.*

³³ See Federal Food, Drug and Cosmetic Act, 21 U.S.C. 331 (2007). Relevant to online pharmacy regulation, the FD&C prohibits “[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.” *Id.* It also prohibits “[t]he doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.” *Id.*

³⁴ 21 U.S.C. § 801 et. seq.

³⁵ Linda Bren, Agencies Team Up in War Against Internet Health Fraud, <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismAndDrugPreparedness/ucm137264.htm>. The Federal Trade Commission (FTC) has played a somewhat smaller role in regulating online pharmacies. In 2001, the FTC created “Operation Cure.All” to crack down on companies making fraudulent health product claims. Operation Cure.All resulted in numerous product seizures and recalls, arrests, and convictions. *Id.*

³⁶ FDA’s Mission Statement, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Feb. 12, 2009). A portion of the FDA’s Mission Statement reads :

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Wiley Act was passed in 1906.³⁷ The Wiley Act placed the Bureau of Chemistry in charge of label regulation.³⁸ At its inception, and until 1912, the FDA was primarily focused on regulating food, rather than drug products.³⁹

The FD&C was first passed in 1938 after a series of tragic and needless deaths.⁴⁰ The FD&C “brought cosmetics and medical devices under control, and it required that drugs be labeled with adequate directions for safe use . . . and mandated pre-market approval of all new drugs.”⁴¹ This meant that drugs needed FDA approval before manufactures or anyone else could sell them.⁴² The FDA regularly uses these provisions as its foundation in online pharmacy regulation.⁴³ A common scenario where the duty to regulate an online pharmacy falls on the FDA usually involves a website purporting to sell cures for cancer, AIDS, etc.

The FDA has dedicated extensive effort toward educating the public concerning the risks and benefits of purchasing medicine from an online pharmacy.⁴⁴ Aware of the rapid increase in online pharmacy sales,⁴⁵ the FDA’s praise of online pharmacies

³⁷ John P. Swann, FDA History—Part I: The 1906 Food and Drugs Act and Its Enforcement, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> (last visited Oct. 31, 2009). After 1912, the Bureau of Chemistry focused its efforts on “patent medicines” in an increased effort to regulate drugs. Although frustrated by regulatory laws, “seizures of misbranded and adulterated drugs nevertheless increased in the 1920s and 1930s.” *Id.*; What FDA Regulates, <http://www.fda.gov/comments/regs.html> (last visited Feb. 12, 2009). Currently, the FDA regulates a wide array of products. Categorically, the FDA regulates biologics, cosmetics, drugs, foods, medical devices, radiation-emitting electronic products, and veterinary products. *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Buying Prescription Medicine Online: A Consumer Safety Guide, <http://www.fda.gov/Drugs/ResourcesForYou/ucm080588.htm> (last visited Oct. 31, 2009). One example of the effort to educate internet consumers, offers a practical guide that explains the basic risks and recommendations when dealing with an online pharmacy. *Id.* The guide breaks down the different risks of the websites versus the risks of the medicine. *Id.* Website risks include dealing with an unlicensed body a potential lack of privacy. *Id.* Medicine risks, however, pose serious health risks. *Id.* The FDA also advises consumers to meet and talk to their doctor. *Id.* Finally, the guide provides links to reputable websites designed to help consumers find legitimate online pharmacies, as well as links to additional online pharmacy consumer education information. *Id.*

⁴⁵ William K. Hubbard gave testimony before the United States House of Representatives in an effort to bring the major issues associated with the growing online pharmacy industry to light. Hubbard explained that “[w]ith greater and greater frequency, consumers are using the Internet to access health related information and products. Sales of consumer products over the Internet have grown rapidly, including the sale of drugs.” Internet Prescription Drugs: Hearing Before the H. Comm. On Government Reform 108th Cong. (2004) (statement of William K. Hubbard, Associate Comm’r for Policy and Planning, Food and Drug Administration).

exclaim that pharmacies have provided “significant benefits to consumers.”⁴⁶ William K. Hubbard, of the FDA, testified before the United States House of Representatives that “[m]any managed health care organizations are . . . turning to online prescription plans as a means of providing quality service at a lower cost.”⁴⁷ The advantages offered by online pharmacies include convenient and open access to drugs for disabled or homebound consumers, wider selection, lower prices, 24-hour shopping, and privacy.⁴⁸ Additionally, technological aspects such as e-mail reminders, hyperlinks, and access to drug information can be substantial advantages over brick and mortar pharmacies.⁴⁹

The FDA devotes comparatively little effort praising online pharmacies in relation to the effort spent warning consumers concerning the risks of purchasing medicine through an online pharmacy. Much of the FDA’s concern relates to the practices of remote consultation and rogue pharmacies. The FDA describes these pharmacies as “a serious potential threat to the health and safety of American citizens.”⁵⁰ The list of FDA risk concerns from internet pharmacies includes dangerous side effects from incorrect prescriptions, dangerous drug interactions, drug contamination, outdated and counterfeit drugs.⁵¹

⁴⁶ *Id.*

⁴⁷ Hubbard’s statement in full reads: “The growth in online drug sales by reputable pharmacies has provided significant benefits to consumers. Many managed health care organizations are searching for ways to achieve cost savings and are turning to online prescription plans as a means of providing quality service at a lower cost.” *Id.*

⁴⁸ *Id.*

⁴⁹ Expanding on the benefits of online pharmacies, Hubbard explained that the internet offers advantages in the amount of information available and the ease of obtaining it, for example “detailed information on drug interactions . . . e-mail [notification] if the drug they ordered has been recalled [or] a cheaper generic version of the drug becomes available . . . [h]yperlinks and search programs [that] provide online customers with written product information and references to other sources of health information more easily than in the traditional storefront.” *Id.*

⁵⁰ Nearly five years before the Ryan Haight Act becomes effective, Hubbard’s testimony makes clear that federal regulatory agencies, such as the FDA, were aware of the need to regulate online pharmacies well before the Ryan Haight Act was passed. *Id.* Hubbard cites the American Medical Association and the Federation of State Medical Boards as other regulatory agencies advocating for online pharmacy regulation. *Id.* Hubbard specifically describes the dangers of using remote consultation pharmacies as “practicing what amounts to self-diagnosis” and a means to bypass regulation. *Id.* Before the Ryan Haight Act, the only piece of internet pharmacy targeted legislation, the FDA was limited to advocating voluntary regulatory regimes, such as VIPPS. *Id.* Any FD&C Act violations perpetuated by online entities were handled as if it “were . . . another sales medium, such as a storefront or a magazine.” *Id.* The testimony offered before the U.S. House of Representatives should have been a wakeup call to legislators about the dangers of access to unregulated medicine and controlled substances. *Id.*

⁵¹ *Id.*

The duty to regulate controlled substances was initially that of the FDA through the Drug Abuse Control Amendment of 1965.⁵² The Drug Abuse Control Amendment gave the FDA “control over amphetamines, barbiturates, hallucinogens, and other drugs of considerable abuse potential.”⁵³ However, the duty to regulate controlled substances was eventually delegated to the DEA.⁵⁴ President Nixon created the DEA through an executive order in 1973.⁵⁵ The DEA regulates “[i]llegal drugs with no approved medical use—such as heroin and marijuana.”⁵⁶ The mission statement of the DEA requires the DEA to “enforce the controlled substances laws and regulations of the United States.”⁵⁷

Both the DEA and FDA have published guides to educate consumers about the risk and benefits of online pharmacies.⁵⁸ These guides offer tips on safety, the law, and what to look for in a reputable online pharmacy.⁵⁹ For example, the FDA

⁵² John P. Swann, FDA History—Part III: Drugs and Foods Under the 1938 Act and Its Amendments, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm.055118.htm> (last visited Oct. 31, 2009).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ United States Food and Drug Administration, What FDA Does Not Regulate, <http://www.fda.gov/comments/noregs.html> (last visited Feb. 12, 2009).

⁵⁷ U.S. Drug Enforcement Administration, DEA Mission statement, <http://www.usdoj.gov/dea/agency/mission.htm> (last visited Feb. 12, 2009). The mission statement of the DEA reads:

The mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.

⁵⁸ The United States Food and Drug Administration, The Possible Dangers of Buying Medicines Over the Internet, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm> (last visited Apr. 15, 2010). In yet another effort to inform consumers, the FDA provides easy to read material that explains how consumers can identify whether or not an online pharmacy or its products are legitimate. *Id.*; Drug Enforcement Administration, Office of Division Control, Questions and Answers: Dispensing and Purchasing Controlled Substances Over the Internet, <http://web.archive.org/web/20080722205257/http://www.dea.diversion.usdoj.gov/faq/internetpurch.htm> (last visited Apr. 15, 2010). The DEA also provides consumer friendly and easy to read materials regarding online pharmacies. However, the material from the DEA tends to focus on the criminal aspects concerning rogue pharmacies, whereas the FDA focused on potential health risks. The DEA correctly identifies one of the major issues for rogue sites – many consumers are unaware that they are breaking the law. The educational material is an effort to prevent, rather than punish, those sorts of crimes. *Id.*

⁵⁹ The United States Food and Drug Administration, The Possible Dangers of Buying Medicines Over the Internet, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm> (last visited Feb. 12, 2009); Drug Enforcement Administration, Office of

recommends that the pharmacy should be licensed, located in the United States, require a prescription, and have a pharmacist available for any questions or concerns.⁶⁰ In a similar vein, the DEA advises consumers on common traits of unsafe websites.⁶¹ Unsafe websites are often eager to offer to import illegal or dangerous drugs without a valid prescription.⁶²

B. An analysis of The Ryan Haight Online Pharmacy Consumer Protection Act of 2008

The Ryan Haight Act addresses several issues. Primarily, the Act adds to and amends several sections of the Controlled Substances Act.⁶³ The additions and amendments are specifically directed towards online pharmacies.⁶⁴ These additions are significant because the Ryan Haight Act is really the first piece of major legislation to address online pharmacies directly. The Act reflects both a change in environment and legislative direction.⁶⁵

The DEA's press release highlights six prominent features of the Act,⁶⁶ which will be discussed in depth later in the note. The Act will: (1) require face to face

Division Control, Questions and Answers: Dispensing and Purchasing Controlled Substances Over the Internet <http://web.archive.org/web/20080722205257/http://www.dea.diversion.usdoj.gov/faq/internetpurch.htm> (last visited Apr. 15, 2010).

⁶⁰ Drug Enforcement Administration, Office of Division Control, Questions and Answers: Dispensing and Purchasing Controlled Substances Over the Internet, <http://web.archive.org/web/20080722205257/http://www.dea.diversion.usdoj.gov/faq/internetpurch.htm> (last visited Apr. 15, 2010).

⁶¹ *Id.*

⁶² *Id.* The DEA provides notice of the laws relevant to importing controlled substances with "The Controlled Substances Act prohibits any person from importing into the customs territory of the U.S. any controlled substance or List I chemical (21 U.S.C. § 971) and (21 CFR part 1313) unless that person maintains a valid, current authorization to import such substances or chemicals (21 U.S.C. 957(a)). Illegal importation of controlled substances is a felony that may result in imprisonment and fines (21 U.S.C. 960). *Id.*

⁶³ 110 P.L. 425 (Oct. 15, 2008). The Ryan Haight Act amends 21 U.S.C. § 801, 21 U.S.C. § 802, 21 U.S.C. § 823, 21 U.S.C. § 827, 21 U.S.C. § 829, 21 U.S.C. § 831, 21 U.S.C. § 841, 21 U.S.C. § 843, 21 U.S.C. § 882, and 21 U.S.C. § 960. *Id.*

⁶⁴ *See generally* 21 U.S.C. § 831 et seq; Mike Pramik, New Law regulates internet drug sales, *The Columbus Dispatch*, http://www.columbusdispatch.com/live/content/business/stories/2008/10/17/Internet_pharmacy_law.ART_ART_10-17-08_C12_SUBKEQK.html?sid=101 (last visited Mar. 25, 2009). "Before the law was enacted, the legal definition of what constitutes a prescription had been left to state pharmacy boards." *Id.*

⁶⁵ 110 P.L. 425 (Oct. 15, 2008). While the legislation places online pharmacies on the same regulatory regime as brick and mortar pharmacies, it includes many internet specific provisions. *Id.*

⁶⁶ DEA News: Congress Passes Ryan Haight Online Pharmacy Consumer Protection Act, http://www.prweb.com/releases/DEA/Pharmacy_Act/prweb1409764.htm (last visited Dec. 2, 2008). At the time of the press release, the Act had not been formally signed into legislation by President Bush. DEA Administrator Michele Leonhart stated "[t]his landmark piece of legislation will bring rogue pharmacy operators out of the shadows by establishing a clear standard for legitimate online pharmaceutical sales. The legislation will allow customers to

medical examination before a prescription is issued, (2) require DEA endorsement for pharmacies, (3) increase penalties for distributing certain drugs, (4) prohibit advertising illegal drug sales, (5) require pharmacies to post relevant contact information, and (6) create a civil cause of action for state attorneys general.⁶⁷

1. Strengths of the Ryan Haight Act

2. DEA Endorsement⁶⁸

Under the Controlled Substances Act, brick and mortar pharmacies that dispense Schedule II, III, IV, or V drugs⁶⁹ must register with the Drug Enforcement Administration⁷⁰ and state attorney generals. Before the Ryan Haight Act, online pharmacies were not required to register with the DEA. Online pharmacies were only required to register the “actual physical location of the pharmacy which purchases, stores and dispenses controlled substances pursuant to prescription orders processed by the Internet site.”⁷¹ Now, the DEA contends that online pharmacies will be put on “equal footing” with brick and mortar pharmacies by the Act because all DEA “shall modify the registration of pharmacies . . . to dispense controlled substances by means of the internet.”⁷²

know they are doing business with a trusted, legitimate pharmacy, and give law enforcement the tools we need to identify illegitimate online pharmacies.” *Id.*

⁶⁷ *Id.*

⁶⁸ 21 U.S.C. § 823 (b) (2008). Pharmacies registered to dispense controlled substances will have their registrations modified to “authorize them to dispense controlled substances by means of the internet”. *Id.*

⁶⁹Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 26, at 21181.

“Schedule II - Amphetamine, codeine, fentanyl, Hydromorphone, meperidine, methadone, Methylphenidate (Ritalin),morphine, oxycodone, pentobarbital, phencyclidine(PCP), secobarbital.

Schedule III - Anabolic steroids, phendimetrazine, and products that contain small quantities of certain schedule II controlled substances, such as codeine, in combination with noncontrolled ingredients, such as aspirin.

Schedule IV - Alprazolam (Xanax), chlordiazepoxide (Librium),diazepam (Valium), lorazepam (Ativan), phenobarbital, phentermine.

Schedule V- Buprenorphine and many cough Preparations that contain a limited amount of codeine.”

⁷⁰ 21 U.S.C. § 823 (2006). This section of the Controlled Substances act also allows for distributor and manufacturers to forego the registration requirements in the name of public interest.

⁷¹ 21 U.S.C. § 823 (b) (2008); Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 26, at 21182.

⁷² DEA News: Congress Passes Ryan Haight Online Pharmacy Consumer Protection Act, *supra* note 66. Online pharmacies are put on equal footing with brick and mortar pharmacies for regulatory purposes. The Ryan Haight Act includes several internet specific provisions to facilitate the “equal footing”. *Id.*

The problem before the legislation was evident in the relationship between the online pharmacies and the registered brick and mortar pharmacies. The registered pharmacies would “have little or no walk-in customers and do most or all of their business via rogue Internet sites.”⁷³ This relationship enabled online pharmacies to bypass traditional methods of regulation. Traditional DEA regulation would monitor entities that dispensed the controlled substances for violations of the law. Before the Act, online pharmacies had full access to DEA regulated controlled substances without being registered with the DEA. In other words, many of the pharmacies were simply off or under the radar of the regulating agencies.

Pharmacist Tommy Fuchs presents a vivid illustration of the need for the federal registration requirement. Fuchs established brick and mortar pharmacies in Texas and later in Oklahoma as front for his online pharmacy businesses.⁷⁴ Fuchs’ online pharmacies, in turn, were merely a way to sell pain pills to addicts at an enormous profit. At their peak, the pharmacies filled up to 500 prescriptions for controlled substances from the same doctor each day.⁷⁵ The prescriptions commonly authorized the maximum number of refills, which allowed the consumer to receive as many pills as he or she wanted at a time and the pharmacy to make more money per transaction.⁷⁶ Unfortunately, one of the prescriptions and refill combinations went to Ryan Haight, who was killed from an overdose of the medicine.⁷⁷

Fuchs’ original Texas pharmacy had been shut down by the Texas State Board of Pharmacy after the Board noticed a suspiciously high number of prescriptions were filled by the same doctor.⁷⁸ The Texas Board took all of the necessary action it was authorized to do.⁷⁹ Confined to act under laws designed to regulate brick and mortar pharmacies, the Texas Board was largely unable to prevent series of events that followed. Undeterred, Fuchs simply hopped the state line and picked up where he

⁷³ *Id.*

⁷⁴ *United States v. Fuchs*, 467 F.3d 889,898 (5th Cir. 2006). Fuchs paid staff physicians between \$40 and \$70 for each prescription. *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Testimony of Francine Haight*: Hearing before the S. Comm. On the Judiciary, 110th Cong. (May 16, 2007), available at http://judiciary.senate.gov/hearings/testimony.cfm?id=2755&wit_id=6466 (last visited Feb. 12, 2009). Francine Haight, Ryan Haight’s mother, testified before the Judiciary Committee. In her testimony, Francine relived the events leading up to Ryan’s death, stating “Clayton Fuchs of Mainstreet Pharmacy, delivered [the drugs] to our home.” Francine also read excerpts from letters she has received expressing public support for online pharmacy regulation. *Id.*

⁷⁸ *Fuchs*, 467 F.3d at 897. “Texas State Board of Pharmacy performed a routine inspection of [Fuchs’ pharmacy] . . . [and] was troubled by the high volume of prescriptions. . . [and] also concerned that nearly all . . . prescriptions were signed by the same doctor, who was located in Texas, [although his] patients were dispersed throughout the United States.” *Id.*

⁷⁹ *Id.* The Texas Board of Pharmacy Field Compliance Officer “informed Fuchs that the prescriptions generated through [the website] were invalid.” *Id.*

left off.⁸⁰ One month after being shut down in Texas, Fuchs opened an Oklahoma pharmacy under a different pharmacy name. The Oklahoma pharmacy functioned in the nearly the exact manner as the Texas pharmacy - peddling drugs under a quasi-legal entity.⁸¹ The pharmacies generated millions of dollars and Fuchs fueled addictions across the country by prescribing and shipping pills to whomever was willing to pay.

The federal registration requirement is a much needed element of federal regulation. The registration requirement in the Ryan Haight Act could have prevented the conduct described above. By requiring all internet sites to register, the DEA would be better able to monitor online pharmacies for illegitimate use.⁸² Rather than searching the internet and investigating individual web sites, the DEA could now simply shut down any unregistered site as soon as it is discovered, precluding nefarious pharmacists from crossing state lines, opening a new pharmacy and resuming business as usual.

The nature of the internet is far more conducive to federal regulation than state regulation. The internet is the same for all users, regardless of whichever state a particular user happens to be a part of. Federal agencies are not bound by arbitrary lines – they are free to regulate across all fifty states. The DEA endorsement could also serve as a central database of valid online pharmacies. Ideally, all valid websites would be readily ascertainable in one centralized source, perhaps setting the foundation for cooperation with other government agencies and business entities. Perhaps eventually a published list of DEA endorsed online pharmacies will be available to consumers as to promote safe online transactions. The ability to check the endorsement status of a website may be very reassuring to new or inexperienced online patrons.

a. Transparency and Notice

An additional strength of the Ryan Haight Act is that the Act itself serves as a notice of the government's position on online pharmacies to the public. The underlying theme of the government's message is that all pharmacies will be held accountable to the same regulations and standards, notwithstanding their status as a digital or brick and mortar entity.⁸³ For consumers, the Ryan Haight Act strives to

⁸⁰ *Id.* A field compliance officer from the Texas State Board of Pharmacy performed an inspection of Fuchs' pharmacy in August of 2000. *Id.* The officer was troubled by the amount of prescriptions and the practice of having the same Texas doctor prescribe patients throughout the United States. *Id.* The officer informed Fuchs that the prescriptions were invalid. Fuchs subsequently closed the Texas pharmacy. *Id.* In October 2000, just three short months after closing the original pharmacy, Fuchs opened his Oklahoma pharmacy. *Id.*

⁸¹ “[the Oklahoma pharmacy’s] operation was substantially the same as [the Texas pharmacy].” *Id.* at 898. “The pharmacy was processing between 300 and 500 prescriptions per day, approximately 70% of which were for hydrocodone. And nearly every . . . order was shipped out was a 30 day supply of 100 tablets with two refills.” *Id.*

⁸² DEA News: Congress Passes Ryan Haight Online Pharmacy Consumer Protection Act, *supra* note 66.

⁸³ DEA News: Congress Passes Ryan Haight Online Pharmacy Consumer Protection Act, *supra* note 66. The act will place online pharmacy sales “on an equal regulatory footing with those sales through a brick-and-mortar facility. The act requires an endorsement of an existing registration to allow existing pharmacies to sell controlled substances online . . . [L]aw

place online pharmacies on equal footing with brick and mortar pharmacies in terms of transparency, customer service and compliance with relevant laws.⁸⁴ The Ryan Haight Act requires pharmacy websites to disclose information so commonplace in brick and mortar pharmacies that it may often go unnoticed. For example, online pharmacies are now required to place contact and licensure information prominently on the home page.⁸⁵ Increased transparency will ease the consumer concerns regarding the legality⁸⁶ of the pharmacy and establish consumer trust. While this aspect of the Ryan Haight Act will not deter criminals from trying to bypass controlled substance regulations, it will help consumers avoid falling prey to rogue website fraud.

For prescribing doctors and pharmacists, the Ryan Haight Act serves as a notice of baseline professional conduct and as a warning for those who choose to act outside of professional conduct. The Ryan Haight Act requires a valid prescription before any controlled substance is dispensed.⁸⁷ A valid prescription requires at least one in-person medical evaluation,⁸⁸ putting an end to remote consultation pharmacies as commonly practiced. Remote consultation pharmacies relied on the doctor's ability to issue prescriptions to whoever is willing to fill out a website questionnaire.⁸⁹ Through the use of a questionnaire, one doctor was able to provide service to countless customers from all over the United States, keeping the cost of operating an online pharmacy to a minimum.⁹⁰ It is clear that legislators believe the potential harm from remote consultation pharmacies outweighs the possible benefits of lower cost and at-home service.

The Ryan Haight Act will change the willingness and ability of pharmacists and physicians to dispense drugs illegally. Pharmacists and doctors that ignore minimum guidelines do so at their own peril. Anyone caught violating the Controlled Substances Act will face steeper penalties than before.⁹¹ The scope of

enforcement will be able to . . . scrutinize all applications for such registration . . . easily separate . . . illegitimate Internet operations." *Id.*

⁸⁴ 21 U.S.C. §§ 831(c)(1-7) (2008). Online pharmacies are required to "post in a visible and clear manner" the name and address of the pharmacy, the pharmacy's telephone number and email address, the name and degree and states of licensure of the pharmacist in charge, a list of states in which the pharmacist is licensed, and a certification that the pharmacy is registered to deliver, distribute, or dispense controlled substances over the internet. *Id.*

⁸⁵ 21 U.S.C. §831(c)

⁸⁶ Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 26 at 21183. Under the heading "Are Internet Pharmacy Sites Legitimate?" the DEA encourages readers to confirm the legitimacy of any internet site before filling or ordering a prescription.

⁸⁷ 21 U.S.C. § 829 (2008).

⁸⁸ *Id.* "The term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by -- a practitioner who has conducted at least 1 in-person medical evaluation of the patient. . . ." *Id.*

⁸⁹ *See Ancier, supra* note 15.

⁹⁰ *Id.* at 836. A remote consultation pharmacy is able to serve thousands of consumers from all over the United States through one doctor. *Id.*

⁹¹ 21 § U.S.C.(b)(C, E).

punishable offenses under the Controlled Substances Act applies to all stages of participation in an online pharmacy – from writing the prescriptions to serving as an intermediary for buyers and sellers.⁹² DEA Administrator Michele Leonhart concludes that “[t]he legislation will allow customers to know they are doing business with a trusted, legitimate pharmacy.”⁹³

*b. Striking a Balance between State and Federal Authority*⁹⁴

The Ryan Haight Act creates a state cause of action to better protect consumers and regulate online pharmacies.⁹⁵ The problem before the Act was that “a state Attorney General’s enforcement authority against an online pharmacy is limited to the geographic boundaries of that state, which causes significant challenges when a case involves illegal activity over the Internet.”⁹⁶ Traditionally, pharmacies are regulated by state law while medicine is regulated by federal agencies. States regulate pharmacies through practice licensure. Once licensed by a particular state, pharmacies and pharmacists may dispense FDA regulated or DEA controlled substances.⁹⁷

The state cause of action “allows states to work together with each other and with the federal government to strike the correct balance that will afford consumers the greatest protection without eliminating the states’ traditional role in pharmacy

Schedule III: Maximum sentence for first offenders from 5 years to 10 years;

Maximum sentence for second offenders from 10 years to 20 years;

Schedule IV: Maximum sentence for first offenders from 3 years to 5 years;

Maximum sentence for second offenders from 6 years to 10 years;

Schedule V: Maximum sentence for second offenders from 2 years to 6 years.

⁹² 21 U.S.C. § 841 (2008). The Ryan Haight Act prohibits delivery and distribution of controlled substances by means of the internet, unless authorized by the DEA. Some examples of delivery and distribution provided by the Act are “writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet” and “offering to fill a prescription for a controlled substance based solely on a consumer’s completion of an online medical questionnaire.”

⁹³ DEA News: Congress Passes Ryan Haight Online Pharmacy Consumer Protection Act, *supra* note 66.

⁹⁴ 21 U.S.C. § 882 (2008). “The State shall serve a copy of the complaint upon the Attorney General and upon the United States Attorney . . . Upon receiving notice respecting a civil action pursuant to this section, the United States shall have the right to intervene in such action”. *Id.*

⁹⁵ *Id.*

⁹⁶ DEA News: Congress Passes Ryan Haight Online Pharmacy Consumer Protection Act, *supra* note 66.

⁹⁷ *Hearing on Internet Drug Sales before the H. Comm. On Government Reform*, 108th Congress (2004) (statement of William K. Hubbard, Associate Commissioner for Policy and Planning).

licensing and regulation.”⁹⁸ Under the Act, any state that has reason to believe its residents may be adversely affected by an online pharmacy may bring civil action on behalf of state residents.⁹⁹ The civil action includes injunctive relief, damages, and enforcing compliance.¹⁰⁰ The Act also allows for federal intervention if appropriate.¹⁰¹ The cooperation between state and federal government encourages flexibility necessary to regulate dangerous online entities. State governments may be more able to become aware of a problem pharmacy more quickly than the federal government, but the federal government’s resources may be more effective in combating the problem.

3. Where the Ryan Haight Act falls short

a. Unnecessary legislation

Unfortunately, much of the Ryan Haight Act is dedicated to unnecessary legislation. In a press statement released when the Act was passed, the DEA touts six areas of the controlled substances act that are amended by the Ryan Haight Act that were intended to address the problems caused by online pharmacies.¹⁰² In reality, the Act does not do much in respect to combating rogue and remote consultation pharmacies in at least three of the areas highlighted by the DEA. Those areas are the face-to-face requirement for valid prescriptions, a ban on advertising, and increased penalties for violating the act.

Perhaps one of the most mentioned features of the Act requires a face-to-face meeting between the prescriber and the patient.¹⁰³ The Act also prohibits advertising or offering to fill a prescription based solely on a questionnaire.¹⁰⁴ In 2001, the DEA published a notice to establish guidelines for dispensing and purchasing controlled substances over the internet.¹⁰⁵ In the notice the DEA stated that “[c]ompleting a

⁹⁸ Clifton, *supra* note 5, at 567.

⁹⁹ 21 U.S.C. § 882 (2008).

In any case in which the State has reason to believe that an interest of the residents of that State has been or is being threatened or adversely affected by the action of a person, entity, or Internet site that violates the provisions [The Controlled Substances Act], the State may bring a civil action on behalf of such residents in a district court of the United States with appropriate jurisdiction.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² See Press Release, DEA, *supra* note 66.

¹⁰³ 21 U.S.C. § 829 (2008). “No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.” A valid prescription requires “at least 1 in-person medical evaluation of the patient”. *Id.*

¹⁰⁴ 21 U.S.C. § 841 (2008). The text of the Ryan Haight Act prohibits “offering to fill a prescription for a controlled substance based solely on a consumer’s completion of an online medical questionnaire”. *Id.*

¹⁰⁵ Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 26.

questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship.”¹⁰⁶

In 2005, the DEA released another publication addressing online pharmacies.¹⁰⁷ More specifically, the publication was an attorney’s bulletin explaining why remote consultation pharmacies are illegal.¹⁰⁸ Further, the bulletin offers advice to prosecutors on successful theories of prosecution in combating remote consultation pharmacies.¹⁰⁹ The illegality of remote consultation pharmacies had been established for nearly a decade before the Act’s effective date.

Case law also suggests that the face-to-face meeting requirement in the Act is redundant. In *United States v. Nelson*, a doctor employed by a remote consultation pharmacy was convicted of “conspiracy to distribute controlled prescription drugs outside the usual course of professional practice, in violation of 21 U.S.C. § 846” after filling prescriptions without a face to face meeting with his patients.¹¹⁰ The physician, Nelson, would review patient records and sign the prescriptions as required by federal law. As online consumers filled out questionnaires and requests for prescription drugs, Nelson went to the actual brick and mortar location of the pharmacy to conduct a review of the orders, never speaking or meeting any of the consumers who had placed the order. Some days, Nelson would review up to a thousand questionnaires.¹¹¹ Nelson received compensation for “reviewing” the questionnaires from the owner of the pharmacy. Nelson’s conduct was essentially equal to that of a drug dealer. Customers came to him for drugs, and for a fee, he would aid them in obtaining them. Nelson’s conduct resulted in a conviction for a violation of the Controlled Substances Act.¹¹²

¹⁰⁶ *Id.* at 21183.

¹⁰⁷ *Id.*

¹⁰⁸ *See generally id.*

¹⁰⁹ Charlotte J. Mapes, Internet Pharmacies and the Unlawful Distribution of Controlled Substances, United States Attorney’s Bulletin, Volume 53 Number 5, September 2005 available at http://www.usdoj.gov/usao/eousa/foia_reading_room/usab5305.pdf. In the introduction to the step-by-step advice on how to prosecute online pharmacy operators, the author states that the Food, Drug, and Cosmetic Act and the Controlled Substances Act are used to prosecute drug distributors even though the internet was not in existence at the time of legislation. Mapes proceeds to explain successful prosecution techniques. Mapes concludes, “Internet pharmacy cases are being successfully prosecuted by United States Attorney’s Offices around the country. Such prosecutions can have a substantial impact on the availability of these dangerous drugs. . . .” *Id.*

¹¹⁰ *United States v. Nelson*, 383 F.3d 1227 (10th Cir. Okla. 2004) (held that “the government presented sufficient evidence from which a reasonable jury could find beyond a reasonable doubt that Nelson participated in a conspiracy to distribute prescription drugs outside the usual course of professional practice”).

¹¹¹ Mapes, *supra* note 109. Nelson reviewed “exponentially more [prescriptions] than he could have written if he had seen and consulted with each patient before issuing a prescription.”

¹¹² *Id.* Nelson, a physician, was convicted for conspiracy to distribute controlled prescription drugs outside the usual course of professional practice over the internet. Nelson approved over up to 95% of all internet prescriptions without ever physically examining his patients. The vast majority of the prescriptions were for schedule III painkillers. Nelson

The court in *Nelson* used the very same statute the Ryan Haight Act amends to convict an internet pharmacist.¹¹³ Nelson's conviction was based on a violation of laws established for brick and mortar pharmacists "acting outside the usual course of professional practice."¹¹⁴ The violation of this standard was due in large part to his failure to conduct face-to-face meetings with his patients. Several years later, Congress eventually passed legislation that required the face-to-face meeting in an effort to regulate rogue pharmacies. By adding redundant and already established requirements, the Ryan Haight Act does not contribute in a meaningful way to improve online pharmacy regulation.

In *United States v. Fuchs*, a pharmacist was convicted under the Controlled Substances Act for his participation in a remote consultation pharmacy for dispensing controlled substances via the internet to customers who received prescriptions based solely on questionnaires.¹¹⁵ Fuchs operated a remote consultation pharmacy where customers from anywhere in the United States could place orders for prescription medication through the use of a questionnaire.¹¹⁶ Once the questionnaires were complete, a prescription form was automatically created and sent to the on staff physician.¹¹⁷ After a cursory review, the physician would sign the form and authorize the prescription. Fuchs paid the physician forty dollars for each signed prescription form.¹¹⁸ Fuchs' website was, in essence, a method for consumers to bypass traditional restrictions on controlled substances for a small fee, much like that of a street corner drug dealer.¹¹⁹

United States v. Lovin includes a discussion regarding dispensing controlled substances to customers who completed a questionnaire via the internet when the Ryan Haight Act was still pending legislation.¹²⁰ The *Lovin* court concluded that the

played an integral role in the rogue pharmacy scheme. As the prescribing physician, Nelson personally signed thousands prescriptions to authorizing the pharmacy to distribute the painkillers. *Id.*

¹¹³ *Id.*

¹¹⁴ *United States v. Moore*, 423 U.S. 122, 124 (1975).

¹¹⁵ *Fuchs*, 467 F.3d 889, 898-899 (upholding conviction for conspiracy to distribute controlled substances).

¹¹⁶ *Id.* "Customers located throughout the United States went to the pharmacy's web site, completed an online profile, and requested medication . . . [the doctor] reviewed the patient's profile and approved and signed the prescription without communicating with the patient either face to face or over the telephone." *Id.* at 897.

¹¹⁷ *Id.*

¹¹⁸ *Id.* Fuchs eventually increased the payment to online pharmacy doctors to 100 dollars per prescription after the size of the prescription was changed from 40 pills to 100 pills. *Id.* at 897.

¹¹⁹ DEA News: Congress Passes Ryan Haight Online Pharmacy Consumer Protection Act, *supra* note 66. "Rogue Internet pharmacies typically operate with active participation of an unscrupulous doctor who willingly issues prescriptions to "patients" throughout the country whom the doctor never sees and without a preexisting bona fide doctor-patient relationship." *Id.*

¹²⁰ *United States v. Lovin*, 2008 U.S. Dist. LEXIS 80258, at *10-13 (S.D. Cal. Sept. 29, 2008) (Citing *Quinones*, 536 F. Supp. 2d at 273).

indictment for violations of the Controlled Substances Act were valid even as legislation directly addressing the issues at hand sat unpassed in Congress, stating "[t]hat [even though] Congress has considered clearer legislation . . . does not mean that existing laws do not apply. . . ." ¹²¹ *Lovin, Fuchs, and Nelson* demonstrate that participation in the operation of a remote consultation pharmacy is a violation of the Controlled Substances Act. Formal legislation reaching this conclusion does not provide internet consumers any additional protection. Some commentators are now advocating that the passage of the Ryan Haight Act indicates that remote consultation was previously legal and that current indictments should be thrown out. ¹²² Legislators needed to expand and build on the scope of the existing online pharmacy regulation.

Additionally, the increased penalties in the Act seem largely irrelevant. The increase in prison time is irrelevant largely in part to the scale of the online pharmacy operations. "Stiffer penalties on the sellers of these drugs will not make an appreciable dent in Internet sales. Most of the Web sites offering these drugs are hosted outside the United States, with the sellers well beyond the reach of U.S. law enforcement."¹²³ Successful online pharmacy prosecutions also often result in a wide array of criminal charges. Convictions for conspiracy, money laundering, and continuing criminal enterprise have all accompanied online pharmacy violations of the Controlled Substances Act. ¹²⁴

b. Failure to address Crucial Aspects of Online Pharmacies

Although generally well received, the Act has generated some criticism. ¹²⁵ Perhaps the largest weakness in the Ryan Haight Act is the failure to address important aspects of the online pharmacy industry. Some of the omissions in the Act seem to suggest that the legislators lacked a fundamental understanding of the problems associated with online pharmacies and how they affect consumers. Many of these problems and issues are well documented with private enterprises that rate the validity of online pharmacies. ¹²⁶ The Ryan Haight Act fails to address requirements regarding patient privacy, foreign pharmacies, search engines, and non-controlled substances.

The Ryan Haight Act fails to address any sort of financial or medical record requirement for websites. Identity theft, fraud, and patient privacy are among the first concerns that come to mind for any online transaction, especially when dealing with health issues. While striving to regulate online pharmacies in the same manner

¹²¹ *Id.* at *12.

¹²² *See generally* Donald Cooley, *supra* note 20.

¹²³ Mathea Falco and Philip Heymann, *Fighting the Online Drug Corner*, Washington Post, Mar. 15, 2008, at A13.

¹²⁴ Mapes, *supra* note 109.

¹²⁵ Sarah Rubenstein, *New Bill Targets Rogue Druggists on the Internet*, WALL ST. J., Oct. 9, 2008, at D1, available at http://online.wsj.com/article/SB122351521815117817.html?mod=googlenews_wsj (last visited Oct. 31, 2009).

¹²⁶ National Association of Boards of Pharmacy, <http://www.nabp.net/> (last visited Dec. 5, 2008). Pharmacy Checker.com, <http://www.pharmacychecker.com/aboutop.asp> (last visited Dec. 5, 2008).

as brick and mortar pharmacies, legislators have overlooked problems unique to the internet.

Unregulated medication from foreign pharmacies also poses a threat to consumers. Imported medication may be counterfeit, mislabeled, unsafe, or manufactured under dissatisfactory conditions.¹²⁷ Non-controlled substances, often called “lifestyle drugs”¹²⁸ include hair growth, weight loss, and sexual enhancement medication. Lifestyle drugs do not pose the threat of addiction presented by controlled substance but may still be dangerous if left unregulated.¹²⁹

Finally, the Act bans the use of the internet to “advertise the sale of, or to offer to sell, distribute, or dispense a controlled substance.”¹³⁰ This provision is a good start, but seems to indicate a lack of understanding from the legislators. Google, a leading online advertiser, has already placed self imposed bans on advertising dangerous online pharmacies.¹³¹ Rather, the legislators should have attempted to regulate search engines, which lead consumers to dangerous online pharmacies without the need for the banned advertisements.

IV. RECOMMENDATIONS FOR FUTURE LEGISLATION

Based on the analysis above, the Ryan Haight Online Pharmacy Consumer Protection Act must be amended in order to protect consumers. Future legislation targeted at online pharmacy consumer protection must include regulations for search engines and web intermediaries, patient privacy, foreign pharmacies, lifestyle drugs and drug manufacturers.

A. Web Intermediaries

The Ryan Haight Act appears to ignore the very medium that supports online pharmacies- the internet. Although the Act now *allows* webhosts to shutdown pharmacies that are not properly registered with the DEA,¹³² I recommend that future legislation place more responsibility and accountability with web hosts, search engines, and credit card companies. Domain registration companies have expressed

¹²⁷ United States Food and Drug Administration, <http://www.fda.gov/oc/initiatives/counterfeit/qa.html> (last visited Dec. 5, 2008).

¹²⁸ Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 26 at 21184.

¹²⁹ Kansas ex rel. Stovall v. ConfiMed.com, L.L.C., 38 P.3d 707 (Kan. 2002) (Kansas failed to prosecute a Washington doctor under the Kansas Consumer Protection Act after Viagra, a sexual enhancement drug, was delivered to a 16 year old. The trial court stated “I don’t have any trouble with saying. . . . these people ought to be de-frocked as medical practitioners, as pharmaceutical practitioners. . .”).

¹³⁰ 21 U.S.C. § 843 (2008).

¹³¹ Google, Online Pharmacy Qualifications, http://www.google.com/adwords/pharmacy_qualification.html (last visited Dec. 5, 2008). “Google only accepts online pharmacies that are based in the U.S., Canada, the UK, the Republic of Ireland, Germany, the Netherlands, Australia, or New Zealand and have met certain conditions.”

¹³² A.J. Perez, *New law allows website hosts to just say no to drug*, USA TODAY, Oct. 24 2008, at C7.

support¹³³ for the Ryan Haight Act and even “proposed modifications to make the legislation more relevant”.¹³⁴

In testimony to Congress, William K. Hubbard praised the practices of Google, Yahoo!, Microsoft, and America Online for their voluntary efforts to combat the prevalence of rogue online pharmacies.¹³⁵ He further stated that the FDA has encouraged the cooperation of major online search engines and will continue to do so.¹³⁶ The need to regulate web intermediaries and other internet sales facilitators is well documented. Consumers will not be adequately protected from the ills of internet pharmacies without this crucial step.

Former assistant secretary of state for International Narcotics Matters, Mathea Falco, described the complexity and depth of the role that web intermediaries play by stating

[R]ogue pharmacies operating in lawless locations will continue offering to sell narcotics to teenagers without prescriptions -- or with the phoniest pretense of a prescription -- happily using the unwitting cooperation of U.S. search engines, Internet service providers and credit card companies. We need additional legislation to require the legitimate businesses that are key intermediaries in illegal online drug transactions to withdraw their assistance.¹³⁷

Falco’s concerns with web intermediaries are well founded. Legislation should be established that will either penalize intermediaries that assist illegal online drug transactions or provide incentives to intermediaries that actively resist or take steps to avoid aiding illegal online transactions. Falco offers a solution that combines elements of consumer education and reliance on new technology that would impose relatively simple requirements on search engines:

Search engines that profit from [online pharmacies offering controlled substances] -- should automatically provide a banner warning that such purchases are illegal and describing the dangers of the drugs whenever searches for such terms are requested. In addition, Internet service providers should, in a highly public way, offer customers the use of spam filters to exclude from their homes offers for illegal sales of any controlled substance, such as prescription narcotics.¹³⁸

Falco’s solution protects internet consumers who may unknowingly break the law while offering parents a solution to prevent the sort of behavior that killed Ryan

¹³³ *Id.*

¹³⁴ *Go Daddy Cheers Passage of Online Pharmacy Legislation*, Drug Week, Apr. 18, 2008.

¹³⁵ *Hearing on Internet Drug Sales before the H. Comm. On Government Reform*, 108th Congress (2004) (statement of William K. Hubbard, Associate Commissioner for Policy and Planning, *supra* note 45).

¹³⁶ *Id.*

¹³⁷ Mathea Falco and Philip Heymann, *Fighting the Online Drug Corner*, WASHINGTON POST, Mar. 15, 2008 at A13.

¹³⁸ *Id.*

Haight. The filter would act as a barrier to prevent interested parties from pursuing or following through on advertisements from rogue pharmacies.

B. Patient Privacy

Patient privacy is especially important in online transactions because often, the consumer faces a greater risk of financial or medical data being accessed by a third party than if the consumer were at a local brick and mortar pharmacy. The National Association of Boards of Pharmacy offers two suggestions for consumers when choosing an online pharmacy based on patient privacy. First, the website should encrypt any material that may identify the patient. Next, the website should provide patients with a Notice of Privacy Practices for Protected Health Information. Future legislation should require online pharmacies to encrypt financial and medical information and provide privacy notices.¹³⁹

Two larger online pharmacies, CVS and Walgreens, have extensive sections of their websites responding to patient privacy concerns.¹⁴⁰ Walgreens, for example, is relatively open about what information is disclosed to whom.¹⁴¹ Walgreens' patient privacy policy also suggests that Walgreens has a relatively firm grasp on the patient privacy risks associated with the internet. Perhaps more importantly, Walgreens provides contact information for consumers who may have further inquiries and methods to opt out of some information disclosure programs.¹⁴² The CVS privacy policy is quite similar to that of Walgreens.¹⁴³ CVS explains its policies regarding protecting and sharing information gathered from website visitors, provides contact information, and how it uses the information.

Future online pharmacy patient legislation should draw heavily from existing patient privacy policies of successful and respected pharmacies. Three notice requirements that should be formally legislated are a notice of how the information is stored and used, what information is collected, and to whom what information is disclosed. Additionally, online pharmacies should be required to educate consumers about how their privacy rights may be affected through use of the site that may be different from privacy rights in a traditional pharmacy setting, such as "visits to the Site, which parts of the Site visitors select, IP address (the Internet address assigned

¹³⁹ National Association of Boards of Pharmacy, *supra* note 126.

¹⁴⁰ CVS/pharmacy, Help: Privacy Policy, http://www.cvs.com/CVSApp/help/privacy_policy.jsp (last visited Feb. 12, 2009); Walgreens, Walgreens.com Online Privacy & Security Policy, <http://www.walgreens.com/help/privacyandsecurity.jsp> (last visited Feb. 12, 2009).

¹⁴¹ Walgreens, Walgreens.com Online Privacy & Security Policy, <http://www.walgreens.com/help/privacyandsecurity.jsp> (last visited Feb. 12, 2009). "Categories of personally identifiable information include: name, address, phone number, e-mail address, date of birth, billing/shipping information (credit card number, shipping address), and Rx number." *Id.*

¹⁴² *Id.* "You can always choose not to provide information." Walgreens also provides relevant contact information for consumers who have additional concerns. *Id.*

¹⁴³ CVS/pharmacy, Help: Privacy Policy, http://www.cvs.com/CVSApp/help/privacy_policy.jsp (last visited Feb. 12, 2009). "We want you to understand how any personally identifiable information you provide to us is collected and used. Your personally identifiable information is removed before collected information is passed to the database we use to generate reports." *Id.*

to your computer from your Internet Service Provider), domain type, browser type (e.g., Netscape or Internet Explorer), date and time of day.”¹⁴⁴

Finally, legislation should establish a standard by which all online pharmacies must protect patient privacy. CVS claims to use “reasonable measures”¹⁴⁵ to protect patient privacy. Reasonable measures, according to CVS, include the use of “Secure Socket Layer (SSL) technology . . . SSL technology provides for the safe transmission of personal information . . . because the information is encrypted. Encryption involves systematically scrambling numbers and letters so that if someone managed to intercept a packet of information, they would not be able to make sense of it.”¹⁴⁶ Legislators should implement a flexible patient privacy protection standard for online pharmacies that allows for and anticipates the development of more powerful technology. The standard protection must at *least* use reasonable encryption methods to protect online pharmacy patients in future legislation.

C. Foreign Pharmacies

Foreign pharmacies are particularly troublesome because they are not subject to U.S. laws and regulations. Imported drugs can be especially dangerous.¹⁴⁷ The FDA estimates that up to 30% of imported drugs may be counterfeit.¹⁴⁸ Counterfeit medicine is dangerous simply because consumers may be unknowingly taking life threatening substitutes. For example, the FDA discovered that many consumers who ordered Ambien, Xanax, Lexapro, and Ativan from online pharmacies received products that actually contained haloperidol.¹⁴⁹ The FDA describes haloperidol as “a powerful anti-psychotic drug.”¹⁵⁰

In 2004, the FDA took “action against three foreign internet sites associated with a site previously found to be selling counterfeit contraceptive patches that contain no

¹⁴⁴ CVS.com Privacy Policy, http://www.cvs.com/CVSApp/help/privacy_policy.jsp (last visited Apr. 15, 2010).

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ United States Food and Drug Administration, <http://web.archive.org/web/20080223155318/http://www.fda.gov/oc/initiatives/counterfeit/qa.html> (last visited Apr. 15, 2010).

¹⁴⁸ *Id.* United States Food and Drug Administration, <http://web.archive.org/web/20080223155318/http://www.fda.gov/oc/initiatives/counterfeit/qa.html> (last visited Apr. 15, 2010). The prevalence of counterfeit drugs in developed countries is estimated to be as low as 1%. The FDA asserts that the prevalence of counterfeit drugs in the United States is lower than 1%, not withstanding two recent and highly publicized incidents.

¹⁴⁹ The United States Food and Drug Administration, The Possible Dangers of Buying Medicine Online, *supra* note 58. The side effects for haloperidol are quite serious. The FDA reports that “some sought emergency medical treatment for symptoms such as difficulty in breathing, muscle spasms and muscle stiffness.” The FDA has compiled a list of drugs that consumers should not purchase online due to safety restrictions at www.fda.gov/cder/consumerinfo/dontBuyonNet.htm. *Id.*

¹⁵⁰ *Id.*

active ingredients.”¹⁵¹ The counterfeit patches did not provide any protection against pregnancy. Although outside the jurisdiction of the United States, the FDA was not helpless.¹⁵² The FDA “obtained the cooperation of the U.S.-based internet service provider in shutting down service to these sites.”¹⁵³ On its own initiative, the FDA utilized appropriate web intermediaries to remove the foreign threat.

The FDA has taken measures beyond consumer education and internet service provider cooperation. The FDA also began issuing “cyber letters” in 2000.¹⁵⁴ In a press release, the FDA explains that the cyber letters are

electronic versions that are similar to traditional “warning” or “untitled” letters, which the agency has long sent to organizations or individuals it believes are engaged in violative activities. These letters usually outline the nature of the alleged violation and request a formal response [and] also provide[s]... foreign operators with an explanation of the statutory provisions that govern interstate commerce of drugs in the United States, as well as a warning that future shipments of their products to this country may be automatically detained and subject to refusal of entry.”¹⁵⁵

Not only are drugs from foreign based online pharmacies more likely to be counterfeit or unsafe,¹⁵⁶ they are often more expensive.¹⁵⁷ In 2003, the FDA released

¹⁵¹ The United States Food and Drug Administration, FDA News, FDA Takes Action Against Foreign Websites Selling Counterfeit Contraceptive Patches, <http://www.fda.gov/newsevents/newsroom/pressannouncements/2004/ucm108246.htm> (last visited Apr. 15, 2010).. “[T]he counterfeits were sent in simple plastic zip-lock bags without identifying materials, lot numbers, expiration dating or any other labeling information needed to safely and effectively use this prescription product.” *Id.*

¹⁵² *Id.*

¹⁵³ *Id.* “FDA’s Office of Criminal Investigation is continuing to work with the Department of Homeland Security’s Bureau of Immigration and Custom Enforcement (ICE) Cyber Crimes Center to combat pharmaceutical counterfeiting and other illegal internet drug sales and take effective action against those responsible.” *Id.*

¹⁵⁴ United States Food and Drug Administration, Cyber Letters 2008, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/CyberLetters/default.htm> (last visited Oct. 30, 2009); One such cyber letter was sent to www.cura-care.com, a website that purported to sell cancer treating creams and drugs. On its website, Cura-Care.com described the effects of one its products with the following description: “cancer on the surface of the skin tissue is treated and the deep penetrating delivery cream then allows the active constituents to penetrate the skin and attack the whole cancer hidden beneath the skin tissue.” Available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048289.htm> (last visited Oct. 30, 2009).

¹⁵⁵ FDA Talk Paper, FDA Launches “Cyber” Letters Against Potentially Illegal, Foreign Based Online Drug Sites, <http://web.archive.org/web/20080229052621/http://www.fda.gov/bbs/topics/ANSWERS/ANS01001.html> (last visited Apr. 12, 2010). At the time of the press release, the FDA had only received one response from the cyber letter program indicating compliance to cease illegal activities.

¹⁵⁶ Drugs imported from Mexican pharmacies contained no active ingredients, FDA Talk Paper, FDA Warns Consumers About Counterfeit Drugs Purchased in Mexico, <http://web.archive.org/web/20080223122244/http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html> (last visited Apr. 12, 2010).

a statement proclaiming “[i]n the U.S., generic drugs, which comprise roughly half of all prescriptions, are cheaper than both Canadian branded drugs and Canadian generic drugs.”¹⁵⁸ In an examination of over 2000 drug packages at the United States border, “47 percent of the sampled products can be bought for \$4 at several national chain pharmacies, a price often lower than the shipping costs for the same drugs purchased online.”¹⁵⁹

Existing regulations in the Controlled Substance Act already prohibit importing controlled substances.¹⁶⁰ Because drugs are still commonly imported anyway, some scholars have made some unconventional suggestions ranging from simply lowering the cost of prescription costs in the United States¹⁶¹ to forming an international coalition of online pharmacies.¹⁶² While there is debate as to the foreign pharmacy solution, federal legislators must not continue to ignore the problem.

D. Lifestyle Drugs

Lifestyle drugs are among the most popular items on online pharmacies. Examples of lifestyle drugs include weight loss and sexual enhancement drugs, which are not regulated by the Controlled Substances Act.¹⁶³ While drugs of this

¹⁵⁷ Food and Drug Administration, U.S./Canadian Price Comparisons October 2004, <http://web.archive.org/web/20080504232457/http://www.fda.gov/oc/opacom/hottopics/importdrugs/canadarx.html> (last visited Apr. 12, 2010). The chart compiled by the FDA indicates that for many consumers, drugs purchased domestically are far less expensive. The prices for the Canadian drugs do not include a shipping charge, which is usually between \$15.00 - \$30.00. *Id.*

¹⁵⁸ Food and Drug Administration, FDA White Paper, Generic Drug Prices in the U.S. Are Lower Than Drug Prices in Canada, <http://web.archive.org/web/20080223160716/http://www.fda.gov/oc/whitepapers/drugprices.html> (last visited Apr. 12, 2010). “In the U.S., generic drugs, which comprise roughly half of all prescriptions, are cheaper than both Canadian branded drugs and Canadian generic drugs.” *Id.*

¹⁵⁹ Food and Drug Administration, FDA News, FDA Says Consumers Continue to Buy Risky Drugs Online, <http://web.archive.org/web/20080223200918/http://www.fda.gov/bbs/topics/NEWS/2007/NEW01735.html> (last visited Apr. 12, 2010). The FDA conducted a study of drugs mailed to consumers from outside the United States. Most of the drugs purchased by consumers were domestically available and several had inexpensive generic versions. The FDA’s deputy commissioner for policy suggests that “many people are buying drugs online not to save money but to bypass the need for a prescription from their doctor since these Web sites typically do not require the purchaser to have a prescription.” *Id.*

¹⁶⁰ 21 U.S.C. § 952 (2006). “It shall be unlawful to import . . . into the United States from any place outside thereof, any controlled substance in schedule I or II. . . [or] [n]on narcotic controlled substances in schedule III, IV, or V.” *Id.*

¹⁶¹ Ayers, *supra* note 5.

¹⁶² Yoo, *supra* note 5.

¹⁶³ Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 26; See Drug Enforcement Administration, Office of Division Control, Questions and Answers: Dispensing and Purchasing Controlled Substances Over the Internet, *supra* note 58. “Some people have applied the phrase ‘lifestyle drugs’ to certain medications, such as Viagra, weight control medications, and tranquilizers. Many of these so-called life style drugs are not controlled substances.”

type do not typically present a danger of addiction, they may still pose a danger to individuals with medical complications.¹⁶⁴ Lifestyle drugs, especially weight loss and sexual enhancement drugs, are potentially dangerous to consumers with health problems.

In *Kansas ex rel. Stovall v. ConfiMed.com, L.L.C.*, an attorney general was able to enjoin an out of state vendor from selling and dispensing medication to Kansas residents after a sixteen year old obtained Viagra through an online questionnaire. Ordinarily, teens would be unable to obtain Viagra without first consulting with a physician. With the help of the internet, the teen was able to easily purchase the Viagra. The Attorney General was hampered in his attempts to punish the vendor. In the absence of legislation targeted at online pharmacies dispensing lifestyle drugs, the Attorney General was forced to pursue a prosecution for unconscionable acts under the Kansas Consumer Protection Act. The attempt failed, and the vendor was spared of any meaningful consequences.¹⁶⁵

Weight loss pills and sexual enhancement and erectile dysfunction pills are targeted toward online consumers, often for privacy reasons. Consumers purchasing weight loss or erectile dysfunction tablets may not want to be seen buying said products at the local pharmacy, so they turn to the all too anonymous realm of online pharmacies. The problem, however, is that because lifestyle drugs (also sometimes called “dietary supplements”) are not subject to prescription or controlled substance requirements, there is often little regulation to protect the consumer.¹⁶⁶

Men, the FDA warns, should take care when ordering so called “dietary supplements” because they often “contain prescription drugs or other undisclosed ingredients that can be harmful.”¹⁶⁷ The FDA found that more than one third of the dietary supplements that claimed to increase sexual enhancement contained prescription drug ingredients.¹⁶⁸ Undisclosed prescription drug ingredients can be

¹⁶⁴ Lifestyle Drug Binge, Businessweek.com, http://www.businessweek.com/magazine/content/07_27/b4041048.htm (last visited Mar. 24, 2009). “On June 13 a panel of FDA advisers voted unanimously not to recommend a weight-loss treatment called Acomplia Though it is already approved in 37 countries, the FDA and its advisers are concerned about reports linking it to depression and even suicidal tendencies.” *Id.*

¹⁶⁵ *ConfiMed.com, L.L.C.*, 38 P.3d at 707 (failure to perform physical examination or provide actual physical supervision and Viagra sale to a minor was not unconscionable). “[F]inding . . . that there was no actual harm, nothing was misrepresented, and the product furnished was authentic conclusively shows that potential unconscionable acts outside the enumerated examples of [Kansas Consumer Protection Act] were considered.” *Id.*

¹⁶⁶ See generally Paula Kurtzweil, An FDA Guide to Dietary Supplements, http://www.fda.gov/FDAC/features/1998/598_guid.html (last visited Mar. 24, 2009).

¹⁶⁷ United States Food and Drug Administration, Buying Fake ED Products Online, <http://web.archive.org/web/20080221175443/http://www.fda.gov/consumer/updates/erectiledysfunction010408.html> (last visited Feb. 12, 2009). “Men looking online for ‘dietary supplements’ to treat erectile dysfunction (ED) or enhance their sexual performance should beware: these products may contain prescription drugs or other undisclosed ingredients that can be harmful.” *Id.*

¹⁶⁸ *Id.* “Six of the 17 products we bought contained sildenafil (the active ingredient in Viagra) or a substance similar to either sildenafil or vardenafil,” says [Linda Silvers, leader of FDA’s Internet and Health Fraud Team]. Vardenafil is the active ingredient in Levitra, another FDA-approved prescription drug that treats ED.” *Id.*

potentially dangerous for consumers with “diabetes, high blood pressure, high cholesterol, or heart disease.”¹⁶⁹ On a similar note, the FDA released a list of recalled dietary supplements that were advertised as weight loss pills.¹⁷⁰ The weight loss pills, most of which were obtained from online pharmacies, were recalled because “they contain undeclared ingredients and, in some cases, contain prescription drugs in amounts that greatly exceed their maximum recommended dosages.”¹⁷¹ As it stands, the Ryan Haight Act will not do anything to regulate the trade of lifestyle drugs or dietary supplements via online pharmacies. Congress must address dangerous distribution of medication by irresponsible online pharmacies.

E. Drug Manufacturers

As the ultimate source of prescription medication, legislators must not ignore the role that drug manufacturers play in allowing drugs to be readily distributed by dangerous online pharmacies. *Kelly v. Qualitest Pharmaceuticals, Inc.* involved a surviving family member and a drug manufacturer in a wrongful death suit. The *Kelly* court provided a detailed description of the dangerous relationship between drug manufacturers and online pharmacies.

Online pharmacies . . . are able to purchase virtually unlimited supplies of controlled substances from manufacturers... which employ specific distributors to market the manufacturer’s products. The distributors, with the authority of the manufacturer, allow the drugs which are governmentally regulated because of the dangers the drugs present if improperly used, to enter the stream of commerce unrestrained.”¹⁷²

Later in the opinion, the court declined to extend tort liability to the manufacturer because “[i]t does not appear that Qualitest was a party to the on-line transaction,

¹⁶⁹ United States Food and Drug Administration, Buying Fake ED Products Online, [Http://www.fda.gov/consumer/updates/erectiledysfunction010408.html](http://www.fda.gov/consumer/updates/erectiledysfunction010408.html) (last visited Feb. 12, 2009). The FDA provides a list of erectile dysfunction products sold online to avoid. The list is available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048386.htm> *Id.*

¹⁷⁰ Food and Drug Administration, FDA News, FDA Expands Warning to Consumers About Tainted Weight Loss Pills, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116998.htm> (last visited Feb. 12, 2009). “December 22, 2008, FDA warned consumers not to purchase or consume 28 different products marketed for weight loss. Since that time, FDA analysis has identified 41 more tainted weight loss products that may put consumers’ health at risk.” *Id.*

¹⁷¹ *Id.* “An FDA analysis found that the undeclared active pharmaceutical ingredients in some of these products include sibutramine (a controlled substance), rimonabant (. . . not approved for marketing in the United States), phenytoin (an anti-seizure medication), phenolphthalein (. . . used in chemical experiments and a suspected cancer causing agent) and bumetanide (a diuretic).” *Id.*

¹⁷² *Kelly v. Qualitest Pharms., Inc.*, 2006 U.S. Dist. LEXIS 65814 (E.D. Cal. Aug. 28, 2006), at *4 (Plaintiff’s allegation that Defendant was “negligent in the sales, distribution, and control of the dangerous and controlled substance . . . [and] approved the sale . . . to . . . ‘rogue’ pharmacies without reasonable investigation into the business practices of the pharmacy. . . [and] did not require proof of proper licensing of the business, its pharmacists or physicians” was dismissed for lack of proper venue).

rather, the only apparent role that Qualitest played was manufacturing [the drug].”¹⁷³ If online pharmacies are to be safely regulated, their source for these medications must be controlled. In order to create truly effective online pharmacies, drug manufacturers must be required to conduct “a reasonable investigation into the practices, licensure, and insurance status of the pharmacies”¹⁷⁴ before shipping or selling medication to online pharmacies.

I recommend that future federal online pharmacy regulation should be modeled after the California statute cited in *Kelly*.¹⁷⁵ The statute reads, in part, “No wholesaler or manufacturer . . . shall furnish controlled substances for other than legitimate purposes.”¹⁷⁶ California defines *mens rea*¹⁷⁷ as “knowing, or having conscious disregard for the fact, that the controlled substances are for other than a legitimate medical purpose”¹⁷⁸ If adopted on a federal level, this statute would impose a duty on drug manufacturers to sell controlled substances to legitimate online pharmacies. If taken further, future legislation could limit the sale of controlled substances solely to DEA endorsed pharmacies.

V. WHY THE RYAN HAIGHT WILL BE SUCCESSFUL

The Ryan Haight Act will likely be successful in regulating online pharmacies because other industries have succeeded in the transition from brick and mortar to an online presence. The Ryan Haight Act legislation represents themes of consumer rights and protection, a transition to federal regulation, a transition to internet-based services and the growing recognition of the need for regulation to keep pace with advances in technology. These themes are consistent with successful legislation exemplified in other sectors.

A. Online Banking

The transition of the banking industry away from brick and mortar to online banking¹⁷⁹ draws many similarities to the transition that pharmacies are undergoing. The regulation of online banking, like that of online pharmacies, strives to put brick and mortar institutions on the same ground as online entities. One method of

¹⁷³ *Id.* at *31.

¹⁷⁴ *Id.* at *28.

¹⁷⁵ Cal. Health & Saf. Code § 11153.5 (1988).

¹⁷⁶ *Id.*

“Factors to be considered in determining . . . [mens rea] shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.” *Id.*

¹⁷⁷ Black’s Law Dictionary (8th ed. 2004), *mens rea*. Black’s Law Dictionary defines *mens rea* as “The state of mind that the prosecution, to secure a conviction, must prove that a defendant had when committing a crime.” *Id.*

¹⁷⁸ Cal. Health & Saf. Code § 11153.5

¹⁷⁹ Online banking as extension of brick and mortar banks are often called “bricks and clicks” banking.

achieving this has been to amend a successful regulatory framework that is already in place to reflect technological advances. Just as the Ryan Haight Act amended the Controlled Substances Act, the Federal Reserve's lettered regulations have been amended to reflect changes in technology. For example, "Regulation E" was implemented to regulate electronic fund transfers.¹⁸⁰

To the consumer, online banking offers many of the same advantages and risks associated with online pharmacies. The advantages in online banking revolve around convenience, efficiency, speedy transactions, and the ability to bank from anywhere with internet access. The risks, although not life threatening, are still very serious. The risks of online banking revolve around trust and the potential of fraud. To address the risks, a great deal of banking regulation has been geared toward consumer protection and disclosure requirements. The Federal Deposit Insurance Corporation (FDIC) published a brochure to educate consumers on how to avoid the perils of online banking¹⁸¹ that seems to mirror many of the consumer education publications put out by the FDA¹⁸² and DEA.¹⁸³

The similarity between the efforts of online banking regulations and online pharmacy regulations are striking. In its brochure, the FDIC warns consumers to "[c]onfirm that an online bank is legitimate and that your deposits are insured, [k]eep your personal information private and secure, [u]nderstand your rights as a consumer, and [l]earn where to go for more assistance from banking regulators."¹⁸⁴ With the exception of privacy, the above requirements look as if they were drawn from the Ryan Haight Act. In both banking and pharmacies, online trust is established through the use of an endorsing agency, be it the FDIC or DEA.

Next, banks are required to make certain disclosures, exemplified by the Truth in Lending act. The Truth in Lending Act requires banks to disclose lending terms and arrangements – which are essential to informing and protecting the consumer concerning banking practices.¹⁸⁵ The Ryan Haight Act also requires disclosure of information essential to the safe and successful operation of a pharmacy dispensing

¹⁸⁰ 12 C. F. R. § 205.1, *et seq.* (1996). The amendment to Regulation E "establishes the basic rights, liabilities, and responsibilities of consumers who use electronic fund transfer services and of financial institutions that offer these services. The primary objective of the act and this part is the protection of individual consumers engaging in electronic fund transfers." *Id.*

¹⁸¹ Federal Deposit Insurance Corporation, Safe Internet Banking, <http://www.fdic.gov/BANK/INDIVIDUAL/ONLINE/safe.html> (last visited Feb. 12, 2009). "As use of the Internet continues to expand, more banks . . . are using the Web to offer products and services . . . [to] consumers. The Internet offers the potential for safe, convenient new ways to shop for financial services and conduct banking business, any day, any time. However, safe banking online involves making . . . decisions that will help you avoid costly surprises or even scams." *Id.*

¹⁸² Buying Prescription Medicine Online: A Consumer Safety Guide, <http://www.fda.gov/buyonlineguide/> (last visited Feb. 12, 2009).

¹⁸³ *See* Dispensing and Purchasing Controlled Substances over the Internet, *supra* note 26

¹⁸⁴ Federal Deposit Insurance Corporation, Safe Internet Banking, <http://www.fdic.gov/BANK/INDIVIDUAL/ONLINE/safe.html> (last visited Feb. 12, 2009).

¹⁸⁵ *See generally* 15 U.S.C. § 1601 *et seq.* (1968).

potentially deadly drugs, such as the name of the pharmacist and how to contact the pharmacy.

Banking's track record of successful regulation, smooth transition onto the internet, and emphasis on consumer protection, demonstrate that federal regulation may be appropriate for online activities that were once only done in brick and mortar facilities, such as purchasing and selling medication. Additionally, many of the consumer regulations in the banking industry, such as disclosure and the use of an endorsing agency, are parallel to the consumer regulations in the Ryan Haight Act. The continued growth in online banking demonstrates that consumers are willing to make the transition to online entities when proper consumer protection exists.

B. Increasing Role of the Internet

For both legislators and the public at large, it is becoming harder and harder to ignore the influence of the internet. The internet is fast becoming ubiquitous as its presence seems to increase daily. According to the Pew Internet & American Life Project, an initiative of the Pew Research Center, more than half of American households have high-speed internet access.¹⁸⁶ The Pew Internet & American Life Project also reports that the fastest growing group of internet users is over 70 years old.¹⁸⁷ It is not unreasonable to assume that an increasing population of seniors on the internet will contribute to the growth of online pharmacies. As the percentage of the population that may be exposed to potentially dangerous online pharmacies grows, the demand for effective regulation will become harder to ignore.

VI. CONCLUSION

In sum, The Ryan Haight Online Consumer Protection Act of 2008 is a much needed first step toward meaningful regulation of online pharmacies. The DEA registration, efforts to increase online pharmacy transparency, public notice and balance, serve as strengths of the Act. However, several of the Act's shortcomings must be addressed in future legislation. Improvements for future legislation must address aspects of online pharmacies unique to the internet, such as web intermediaries, web hosts, and patient privacy concerns. The regulation must also be expanded to include readily available and often dangerous lifestyle drugs. Larger problems, such as the liability of drug manufacturers and foreign pharmacies must also be addressed in any future legislation.

¹⁸⁶ Pew Internet and American Life Project, Home Broadband 2008, http://www.pewinternet.org/PPF/r/257/report_display.asp (last visited Feb. 12, 2009). The Pew Internet and American Life Project reports that in 2008, 55% of Americans had high-speed internet access, up from 47% in 2007. *Id.*

¹⁸⁷ SeniorJournal.com - Senior Citizens Information and News, Senior Citizens and Internet, <http://www.seniorjournal.com/NEWS/WebsWeLike/2009/20090207-FastestGrowing.htm> (last viewed Feb. 12, 2009); Sydney Jones, Pew Research Center Publications, Generations Online in 2009, <http://pewresearch.org/pubs/1093/generations-online> (last visited Feb. 12, 2009).