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INTRODUCTION

{1} In today's rapidly changing world of e-commerce, almost anything can be bought over the Internet and delivered right to your front door.¹ Virtually everyday there is news of yet another company selling some type of product online.² Included in this barrage of products is prescription medication.³ Not only is it possible to order prescription medication over the Internet, in some cases it is not necessary to be examined, or even to consult with a physician.⁴ To some, this new type of "cybermedicine" is an affront to traditional medicine, as well as potentially dangerous to consumers.⁵ In addition, the availability of medication over the Internet presents a vexing and complex challenge to state and federal agencies charged with enforcing drug laws.⁶ This problem has recently led to the Commerce Committee of the U.S. House hold hearings on the subject in an effort to understand what is involved with this new type of medicine, and which federal and state agencies have jurisdiction over on-line prescription sales.⁷ Unfortunately, it still remains unclear as to exactly which agencies do have jurisdiction.⁸ Nevertheless, as Congress and individual states rush to address the issue, entrepreneurs and drugstore chains are racing to establish the next on-line pharmacy.⁹

{2} For consumers, the idea of dealing with a “cyber-pharmacy” is appealing for several reasons. Lower cost and convenience for elderly people or those living in rural areas, as well as the ability to privately consult with a pharmacist are just a few of the benefits often cited.¹⁰ But in addition to these advantages, there are still substantial risks.¹¹ These include easy access to illegal or unapproved drugs, medication offered without a prescription, and drugs marketed with fake health claims.¹² As the confusion over online pharmacies mounts, one thing is clear; this new type of medicine is growing at a substantial rate.¹³

{3} This comment will attempt to define and explain the tremendous growth of online pharmacies. Next it will examine pending legislation and current cases relating to the sale of medication online. Finally this comment will examine the risks and benefits of ordering medications online, and what consumers should do to protect themselves as well as comply with the law.

I. THE LEGALITY OF ONLINE PRESCRIPTION DRUG SALES

A) A New Type of Medicine:

{4} Given the amazing rise of e-commerce and the Internet’s regulation-free environment, it’s no wonder that pharmacies and doctors are seeking to take advantage of the new opportunities.¹⁴ However, recent action by several states suggests entrepreneurs need to be extremely cautious when pursuing this new approach to medicine.¹⁵ Cybermedicine has the potential to offer great benefits to consumers, but it can also lead to very serious health consequences if practiced recklessly.¹⁶ Furthermore, this industry is so new and fast growing that it is not clear which practices are legal and which are prohibited by state or federal law.¹⁷

B) Different Types of Medicine-Online Web Sites:

{5} The ability to distinguish between the various types of medical online sites is helpful in understanding the issues in some current cases. Generally, there are three types. First, there are the sites which offer traditional pharmacy services online only. These pharmacy-only based sites will only dispense medicine to a consumer who has first obtained a prescription from a doctor and then submits it to the online pharmacy.¹⁸ Pharmacy-only sites are the least controversial because they do not actually initiate the drug sale. These sites merely process valid prescriptions which have already been obtained from a licensed practitioner. The most significant legal problem with these sites occurs when the pharmacy fails to obtain the appropriate license for each state where it intends to do business.¹⁹

{6} A second category of online pharmacies are prescribing based sites.²⁰ These sites often employ both pharmacists and doctors. However, they should be distinguished from the web sites that also may employ doctors and pharmacists, but only offer medical advice or health related information. This latter type includes thousands of online medical sites and are not the subject of this comment. Usually the prescribing based sites will provide an online doctor visit either through a medical questionnaire or a simultaneous video conference between the doctor and patient.²¹ For this “consultation,” a fee is charged that can range from \$30-\$150.²² After the patient enters the information and the doctor reviews it, a prescription may be issued which is then processed at an online pharmacy. Some prescribing based sites are comprised exclusively of physicians who, upon issuing a prescription, contract with an online pharmacy to actually dispense the medicine.²³ In many cases, the doctor, pharmacy, and patient are all located in different states. The strongest criticism of these sites is that an online form or questionnaire, no matter how detailed, simply cannot substitute for a physical exam. Without an actual face to face exam, critics contend that patient warning signs which might easily be detected by touch, could go unnoticed, posing potential risk to the patient. For this reason,

prescribing based web sites are highly controversial and are the subject of most of the current actions discussed in this comment.

{7} Finally, a third type of online pharmacy is referred to as online drug shops.²⁴ This is an appropriate description because these web sites are primarily engaged in the sale of drugs. Here, essentially all a consumer needs to do in order to obtain a controlled substance or any other prescription drug, is simply go to the site, pick out the drug of choice, and make the purchase with a credit card.²⁵ With these sites, no examination is necessary and no medical questionnaire needs to be answered. Online drug shops often operate from foreign countries and are therefore usually beyond the reach of U.S. authorities. Although many consumers do not realize it, online drug shops are considered illegal by most law enforcement agencies.²⁶ Authorities consider these sites to be the most dangerous because of their willingness to sell potentially dangerous controlled substances, including narcotics, to virtually anyone.²⁷ In addition, online drug shops often sell drugs that are unapproved for medical use in the United States.²⁸ The anonymous nature of the Internet, combined with the fact that many of these pharmacies are foreign based, make them very difficult to stop. In fact, the few online drug shops that are discovered and shut down often reappear the next day under a different name or address, ready again to do business.²⁹

C) Current Cases:

{8} Lawsuits, recently initiated by a few states against doctors and pharmacies, suggest that certain practices are in fact violative of the law.³⁰ For example, an Ohio doctor was recently criminally indicted for “prescribing dangerous drugs over the Internet.”³¹ According to the prosecutor, this was one of the first indictments involving the sale of prescription medicines online.³² The doctor was allegedly operating a prescribing based site, where he was selling “embarrassment drugs” such as ViagraTM and PropeciaTM, and then having them filled at a “cyber-pharmacy” where they would then be shipped off to “patients” all over the country.³³ The violation, according to the prosecutor, was that the doctor, in failing to do appropriate physical examinations, did not establish proper physician-patient relationships, which is necessary under Ohio law before prescription drugs may be issued to new patients.³⁴ This controversy in Ohio is only one of several recent actions by various states trying to bring order to this new, but potentially dangerous practice.

{9} For example, in Illinois state prosecutors have filed lawsuits against out-of-state prescribing based sites, charging that they were not properly licensed to prescribe medicine in the state and that they failed to disclose that information to consumers.³⁵ The state of Illinois joins Kansas and Missouri as the only states, as of yet, to file lawsuits involving Internet drug sales.³⁶ In fact, the Attorney General of Kansas as well as other states’ officials testified at the Congressional hearing as to the troubling aspects involved with online drug sales, including the lack of proper patient-physician relationships.³⁷

D) Pending legislation:

{10} Exactly what can and should be done about online drug sales remains a contentious issue. State officials testifying at the Congressional hearing stressed the important benefits associated with the freedom of the Internet.³⁸ They made clear that while online drug sales are a problem, they are a problem that states, not the federal government, should address.³⁹ It seems clear from testimony at the Congressional hearing, that if pharmacy-only based sites took the time to obtain the requisite licenses in each state that they intend to operate, they would be in compliance with the law.⁴⁰ This sentiment was echoed by the Kansas Attorney General. She stated that as long as Internet doctors and pharmacies are properly state licensed and doing business “by the same standards” as if they were operating on Main street, then the transactions would be fully lawful.⁴¹ In fact, none of the lawsuits, as of yet, have charged that all online prescription drug sales are per se illegal. Instead, all the claims are based on

violations of either state medical, pharmacy, or deceptive business acts. For example, the lawsuits in Kansas, Ohio, and Illinois are all centered on dispensing controlled substances without first establishing proper physician-patient relationships.⁴² Failing to do so is a violation under many state medical and pharmacy acts.⁴³ At least one state, Illinois, has included in its charges the violation of a consumer protection statute, for failing to inform consumers that the doctors or pharmacists working for the site did not have the appropriate licenses to practice medicine in Illinois.⁴⁴

{11} After the Congressional hearing on online drug sales, House of Representative Ron Klink (D-PA) introduced the Internet Pharmacy Consumer Protection Act of 1999.⁴⁵ This act would amend the Federal Food, Drug and Cosmetic Act.⁴⁶ The bill would mandate disclosure of these web sites, requiring them to list its principal place of business, as well as the name and address of any physician or pharmacist working for the site.⁴⁷ In addition, the bill would also require the web site to disclose all of the states where the physicians or pharmacists are licensed to operate.⁴⁸ Representative Waxman (D-CA), a sponsor of the bill, claims that enactment would not only provide law enforcement with greater ability to track down illegitimate sites, it would also provide consumers with a quick and simple way of separating responsible operators from quacks.⁴⁹ According to Rep. Waxman, compliance would be simple and "only asks online pharmacies to provide the same licensure information as brick and mortar pharmacies do when they hang framed licenses on the wall."⁵⁰ In fact, Rep. Waxman says "any person with [basic web programming skills] could ...comply in a matter of minutes."⁵¹ Unfortunately for the sponsors of this bill, any legislation which may somehow impede, or even has the appearance of impeding the growth of the Internet, will face a long difficult road to enactment.⁵²

{12} Most likely, The Internet Pharmacy Consumer Protection Act will not be endorsed by the National Association of Boards of Pharmacy (NABP).⁵³ The NABP is pushing for the industry to self regulate and has launched a new certification system called VIPPS™ (Verified Internet Pharmacy Practice Sites).⁵⁴ VIPPS™ is a voluntary, 17 point rigorous examination, "VIPPS is a voluntary program designed to certify an online pharmacy's preparedness to meet the unique demands of pharmacy practice on the Internet."⁵⁵ Any site earning the VIPPS™ seal must be able to demonstrate compliance with all regulatory, statutory, and licensure requirements of each state it intends to operate.⁵⁶ Before certification is issued, NABP will verify, independently, all pharmacy applications either through on-site inspections or through its computer database of state laws.⁵⁷ This new initiative is quickly gaining acceptance among the industry.⁵⁸ In fact, the first VIPPS™ certifications were recently presented to several major online pharmacies, and already consumer advocates are encouraging consumers to check for the VIPPS™ sign when visiting pharmacy web sites.⁵⁹

{13} However, not everyone feels that this complex issue should be addressed solely by the private sector. During its testimony before Congress, the FTC recognized that even though certification programs such as VIPPS™ can be valuable, legislation requiring disclosure may ultimately be necessary.⁶⁰ In sum, most of the recent initiatives taken by Congress, the states, and private industry all share the common tenet of disclosure. They all in some way require operators to disclose who they are, where they operate, and whether or not they have obtained the requisite state licenses.

E) Who Regulates Cybermedicine?:

{14} Online medicine is developing with such speed that it has caught regulators off guard. The lawsuits, discussed in section C underscore an ongoing frustration of both state and federal regulators as to which agency or agencies has jurisdiction over on-line drug sales.⁶¹ Perhaps part of the problem is that as recent as two years ago, the thought of obtaining prescription drugs from a pharmacy or doctor not located in your home state, or without a prescription, would seem highly remote if not impossible. Today however, this is the reality that officials are facing. It remains to be seen whether or not current laws can be marshaled to adequately address the issue. ⁶²

{15} Compounding the problem is that the practice of Medicine has traditionally been governed by state medical and pharmacy acts. Yet importation of drugs into the U.S, as well as selling them across state lines, is clearly within federal jurisdiction.⁶³ Prescribing based sites and online drug shops involve the practice of medicine, but across state lines. This seems to fall somewhere in between traditional state and federal law. Needless to say, this has created uncertainty and confusion among both federal and state regulators.⁶⁴ To make matters worse, most state acts simply do not directly contemplate the essential premise behind prescribing based medical sites. That is, dispensing medicine to a patient without first performing a physical examination. It is this question which is now hotly debated.⁶⁵ The future of the prescribing based sites will no doubt depend on its outcome. However, until state legislatures or Congress address the issue, there may not be a definitive answer. In the meantime, major medical and pharmacy organizations, including the American Medical Association as well as the NABP, have addressed the issue. They, along with the Justice department, have opined that prescribing based sites that issue new prescriptions based on online questionnaires in lieu of an actual examination, may be in violation of Federal law.⁶⁶ Of course, operators of the prescribing based sites counter that doctors make a lot of money when patients make repeat visits in order to obtain their medication.⁶⁷ By criticizing this new way of obtaining prescription medication, these entrepreneurs charge that the critics are merely guilty of “professional protectionism.”⁶⁸

{16} As of now, it is not clear what will become of many of the prescribing based sites or online drug shops currently doing business. Based on recent actions by several states as well as the federal government, it doesn't look promising, at least in their current form. Pharmacy only sites, on the other hand, are predicted to see exponential growth, and, as long as they obtain the requisite licenses, should stay out of legal trouble as well.⁶⁹

II. THE RISKS AND BENEFITS OF ONLINE MEDICINE

{17} Whether or not one finds online medicine appealing, there is no arguing its growing presence as a viable option of health care.⁷⁰ But by now, the stories of young children and cats receiving prescriptions for Viagra and other “life style drugs,” are well chronicled.⁷¹ Yet these stories do raise serious concerns over the safety of online prescriptions. The Attorney General of Kansas summed them up aptly when she said, “it is only a matter of time before someone, even a child, dies from taking prescription-only medications they purchased over the Internet.”⁷² Of course the risk will vary according to the particular type of online drug sale. The greatest risk lies with prescribing based sites and online drug shops. Here, there is either no doctor interaction at all, or one that is cursory and perhaps insufficient to ferret out any potential problems. With online drug shops, customers can simply go to the site, get a price list of various drugs, and place an order. There is no examination of the “patient” and equally as troubling, there is no disclosure of potential side effects of the medicine being purchased. Many of these online drug shops are located in foreign countries. And many of the drugs that are sold from foreign based pharmacies are not tested at the same high level of quality as drugs manufactured in the U.S.⁷³ Even worse, many of these drugs sold are not FDA approved at all.⁷⁴ Therefore, buying drugs from these web sites can lead to serious health risks. But trying to stop them from operating in this country is complicated, especially if the transaction is legal in the country where it is originating.⁷⁵

{18} In addition, slick web sites can confuse consumers into thinking there is nothing illegal about placing an order for prescription drugs. Potential buyers need to remember though, a drug that requires a prescription from a doctor, doesn't cease to do so merely because it can be purchased on the Internet from the comfort of home.⁷⁶ Even though the chance of being prosecuted for importing a personal quantity of a prescription drug is small, it is still a violation of the law.⁷⁷ Many consumers are unaware of this fact and point to the FDA's personal importation policy as creating an exception to this rule.⁷⁸

However, this policy applies only to certain drugs unavailable or unapproved in the United States.⁷⁹ Drugs which are available in the U.S. and require a prescription, are not covered under the exception.⁸⁰ Therefore, consumers are not only risking their health when they make these purchases from foreign online drug shops, but also, they are potentially breaking the law as well.

{19} The risks with prescribing based sites are also real. Perhaps the biggest risk is to the patients' health. Many prescribing based sites only offer a brief "consultation" with a doctor that might consist of a patient answering a few questions before a prescription is issued. According to many authorities, these sites clearly fall short of establishing the requisite patient-physician relationship.⁸¹ However, some prescribing based sites do offer a very thorough Internet "exam" through video conferencing, rejecting inappropriate patients and only prescribing certain non controlled substances.⁸² Nevertheless, critics contend that drugs have been prescribed too easily to people who turn out to be inappropriate candidates for the medicine.⁸³ This of course can lead to deadly consequences for the person that is unaware of a condition which otherwise would have been exposed by a physical examination. Perhaps, this is why the American Medical Association along with the Federation of American Medical Boards have taken the position that an online questionnaire is no substitute for a genuine examination.⁸⁴ The controversy surrounding the online drug shops and prescribing based sites are far from settled. On the downside, both may entail substantial risks. However, both may also provide legitimate patients who are in need a way of obtaining necessary medication, more conveniently and at a lower cost.

{20} Much less controversial is the pharmacy only sites. Here, there is no doubt that under proper circumstances pharmacy only sites can provide enormous benefits. The principal advantages most often cited are: Lower prices through increased competition among pharmacies; more thorough and private consultations with a pharmacist; greater access to medicine for seniors or people who live in rural areas; speed and ease of choosing and ordering products; comparative shopping among different retailers to get the best deals; and access to a plethora of health care information that is usually unavailable at a conventional pharmacy.⁸⁵

{21} Many of these benefits were confirmed by consumers testifying at the recent Congressional hearing. Among the panel was a senior citizen who testified that as a cancer survivor he is required to take medication on a daily basis.⁸⁶ Constantly traveling back and forth from a conventional pharmacy had become very difficult. By using an online pharmacy, medication could be shipped overnight to his front door, saving time and aggravation. This same sentiment was also shared by another witness who, as a single mom had grown tired of the inconvenience and impersonal treatment she was receiving from the large drug chain store in her neighborhood.⁸⁷ In addition, she had become fed up with repeated mistakes by the pharmacy in filling her medication.⁸⁸ With an online pharmacy, she can not only save time, but also can now consult with her pharmacist more privately than the usual yells behind busy drug store counters.⁸⁹

{22} In conclusion, cybermedicine can offer enormous benefits to consumers. But there are still substantial risks. In buying prescriptions online, consumers will be well advised to adhere to some basic advice. First, as this comment makes clear, be extremely cautious when visiting online drug shops. Unless shopping for drugs which are unapproved or unavailable in the U.S., buying drugs from these sites may do more harm than good. Second, the legal status of many prescribing based sites is still uncertain and may vary from state to state. Therefore, it may not be a great idea to use these sites as a way of purchasing medicine from a new doctor that has not first performed a proper physical examination. Instead, perhaps the best use of these sites may be either to get refills of prescriptions or to get personal medical advice.

{23} When using pharmacy only sites, try to use familiar, reputable pharmacies. One way to accomplish that is to look for the VIPPS™ sign on the web site. This will ensure that the site is a high

quality operation that has undergone rigorous certification. Also, compare prices of several different pharmacies before making a purchase and inquire about delivery and shipping charges. Finally, inquire about the opportunity to consult online with the pharmacist. If there is no available contact with a pharmacist, or no cost savings, or if it takes a week to get the medication, then it might be worth it to stick with the traditional mortar and brick pharmacy.

¹ See, e.g., Steve Lohr, *Ideas & Trends; In E-Commerce Frenzy, Brave New World Meets Old*, N.Y. TIMES, October 10, 1999, at sec. 4, 5 (although traditional retail shopping is still dominant, online retail sales are expected to grow from an estimated \$20 billion this year to \$185 Billion by the year 2004).

² See *id.* (leading online retailer, Amazon.com, announced its intention to start a “Internet shopping bazaar,” where one can purchase almost anything).

³ See, e.g. Joshua Fischman, *Drug Bazaar; Getting Medicine off the Web is easy, but dangerous*, U.S. NEWS & WORLD REPORT, Jun. 21, 1999 at 58.

⁴ See *id.* (U.S. News & World Report conducted an investigation and successfully purchased several different prescription medications, including controlled substances such as Phentermine, a weight loss drug, and Contugesic, a narcotic pain-killer); see also, *Drugstores.com, On-Line Foreign Pharmacies* (visited Jun. 28, 2000) <<http://www.drugquest.com>> (the proprietor of this web site sells, at last check, a publication “How to buy almost any drug without a prescription,” as well as guides listing overseas pharmacies); see also, *Yahoo.com* (visited Jun. 28, 2000) <<http://www.yahoo.com>> (a recent Yahoo search for “buying prescription drugs without a prescription” netted close to 400 results).

⁵ See, e.g. Shari Roan, *Your friendly neighborhood E-Drugstore; The new online pharmacies offer prompt, hassle-free service, but health experts worry that the sites also pose serious potential for misuse*, L.A. TIMES, Sept. 20, 1999, at S1; see also, Val Cardinale, *FDA coming down harder on illegal on-line drug sales*, DRUG TOPICS, Oct. 4, 1999, at 19 (this article cites examples of people illegally obtaining prescription medication).

⁶ See, e.g., Sheryl Gay Stolberg, *Official Struggle to Regulate On-Line Sale of Prescription Drugs*, N.Y. TIMES, Jul. 31, 1999, at A12; see also, Letter from Melinda K. Plaisier, Interim Associate Commissioner for Legislative Affairs, Food and Drug Administration (May 7, 1999) (transcript available on the U.S. House of Representatives web site, <<http://www.house.gov>> at Subcomm. on Commerce of the House Comm. on Oversight & Investigations (this letter responds to a request from Rep. Henry A. Waxman (D.-CA) asking the FDA to address issues related to the sale of medication over the Internet).

⁷ See, *Drugstores on the Net: The benefits and Risks of Online Pharmacies, Before the Subcomm. on Commerce of the House Comm. on Oversight & Investigations*, 106th Cong. 4 (1999) (statement of Rep. Upton) (hereafter referred to as *Hearings*).

⁸ See, Stolberg, *supra* note 6 (the letter addresses the quandary of this matter); see also, Alex Otto, *Congress Working to bring Safeguards to Online Pharmacy; States Seek Power to Levy Nationwide Injunctions*, PHARMACY TODAY, Sept. 1999, at 8.

⁹ See, e.g., *Drug Chains Stake Claims on Internet*, CHAIN DRUG REVIEW, Aug. 16, 1999, at 4; see also, Carol Smith, *Prescriptions in Cyberspace; Virtual Pharmacies Hope To Tap Health Care Market*, SEATTLE POST-INTELLIGENCER, Feb. 1, 1999, at D1 (total prescription drug sales expected to rise from \$100 billion plus last year to \$150 billion over the next four years).

¹⁰ See *Hearings*, *supra* note 7 (statement of Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration); *id.* at 9-17 (statements of consumers Bob Michel and Ellen Yui). But see Stacey Burling, *Study: Online drugstores rarely a bargain*, SAN DIEGO UNION-TRIBUNE, Oct. 5, 1999, Computer Link at 17 (citing a study by researchers at the University of Pennsylvania which compared the prices of two different drugs sold at both online pharmacies and traditional pharmacies. The study revealed that, on average, drug prices on the Internet were 10 percent higher. However, it should be noted that the study was completed in February and March of 1999, which was an early stage of commercial development for on-line prescription sales. In fact, the study looked at all the pharmacy web sites available at the time-only 46. Now there is several hundred if not thousands of online pharmacies.).

¹¹ *Hearings*, *supra* note 7 (statement of Dr. Herman Abromowitz, American Medical Association).

¹² See *id.* (statement of Dr. Janet Woodcock, Food and Drug Administration)

¹³ See, Smith, *supra* note 9 at 1.

¹⁴ See, e.g., Roan, *supra* note 5 at 1 (pharmacy sites alone have gone from a few dozen this year to over 400); see also, *Drug Chains Stake Claims on Internet*, *supra* note 9 at 4 (most large drug store chains already have Internet pharmacies, and of the few that don't, many of them have plans to go online shortly); see also, Smith, *supra* note 9 (expert noting that this booming online market for prescriptions is essentially just the beginning of what is to come).

¹⁵ See, e.g., Tim Doulin and Mark D. Somerson, *Doctor Indicted in Web Drug Case, the Dublin [Ohio] Physician is Charged with Illegally Selling Prescription Drugs to Patients He Never Saw*, THE COLUMBUS DISPATCH, Jul. 10, 1999, at 1A (State of Ohio v. Thompson, No. 99-cr-3644, Ct. Common Pleas, Columbus, OH, complaint filed Jul. 9, 1999); see also, *Ryan Sues to Protect Consumers Against Illegal Sales of Prescription Drugs Over the Internet*, PR NEWSWIRE, Oct. 21, 1999, available in LEXIS, News Library File, (State of IL v. ExpressMed, No. 99-ch-452, Sangamon Cir. Ct., Springfield, IL, complaint filed October 21, 1999).

¹⁶ See, e.g., Cardinale, *supra* note 5 (citing examples of people inappropriately using the web to obtain prescription drugs. For example, one woman obtained a controlled substance for a suicide attempt. In another case, a young anorexic girl was able to obtain a prescription diet drug); see also, Federal Trade Commission release, "Operation Cure.all" Targets Internet Health Fraud; FTC Law Enforcement and Consumer Education Campaign Focuses on Stopping the Quacks and Supplying Consumers with Quality Information, Jun. 24, 1999 <<http://www.ftc.gov/opa/1999/9906/opcureall.htm>> (visited Jun. 28, 2000); see generally, Luran Neergaar, *Increased Internet Drug Purchases Concern Regulators*, THE JOURNAL RECORD, Jan. 6, 1999, available in WESTLAW 1999 WL 9842211.

¹⁷ See Stolberg, *supra* note 6.

¹⁸ See Hearings, *supra* note 7, (statement of Ivan Fong, Assoc. Att’y Gen., U.S. Dep’t of Justice) (The Justice Dep’t, in its testimony, defined the various types of medical online sites; I have attached a label to those definitions to make it easier for discussion. Carmen Catizone, of the NABP, in her statement to Congress, also has attached similar definitions to the various types of medical online web sites).

¹⁹ For a discussion of the consequences of failing to be licensed, *See infra* section C, Current Cases at 8.

²⁰ *See supra* note 18

²¹ *See e.g., Cyberdocs, The Doctor Is Always In* <<http://www.cyberdocs.com>> (visited Jun. 28, 2000) (an example of a prescribing based site).

²² *See id;* *see also*, Fischman, *supra* note 3.

²³ *See Cyberdocs, The Doctor Is Always In, supra* note 21.

²⁴ *See Hearings, supra* note 7 (statement of Ivan Fong, Assoc. Att’y Gen., U.S. Dep’t of Justice).

²⁵ For an example of an Online Drug Shop Web site, go to any standard web browser search engine such as <<http://www.yahoo.com>> and enter the following; “Buying drugs or medicine without a prescription.”

²⁶ *See Hearings, supra* note 7 (statements of Janet Woodcock, Director Center for Food and Drug Research and Evaluation, Food and Drug Administration, and Ivan Fong, Assoc. Atty Gen., U.S. Dep’t of Justice) (If the drug being sought requires a prescription, that requirement doesn’t go away because it happens to be for sale in a foreign pharmacy without a prescription. Buying that drug is a violation of the law, much like it would be if it was bought here on the street. *See also* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §331(a), §353(b). Frequently, web sites will cite the FDA “personal importation policy” as a means by which prescription drugs may be purchased from online drug shops, legally. Unfortunately, consumers are rarely made aware that the FDA policy *only* applies to drugs *unapproved and unavailable in the U.S.* *See U.S. Food and Drug Administration Import Information*, <http://www.fda.gov/ora/import/ora_import_system.html> (visited Jun. 28, 2000).

²⁷ *See Janet Woodcock, Director, Center For Drug Evaluation And Research, U.S. Food and Drug Administration, testimony Before The Subcommittee On Oversight And Investigations Committee On Commerce, U.S. House Of Representatives, Jul. 30, 1999 at* <<http://www.fda.gov/ola/1999/drugsonline.html>> (visited Jun. 28, 2000) (citing an example of an Online Drug Shop located in South America which was selling an abortion kit that posed potentially fatal health risks to women) (Online drug shops can vary greatly in their willingness to sell prescription drugs with or without a prescription).

²⁸ *See id.*

²⁹ *See id.*

³⁰ See, Bill Bell Jr., *Web Drugstore is Barred from Selling in Missouri*, Jul. 9, 1999, available in WESTLAW 1999 WL 3038140 (State of Missouri v. Stallknecht, No. 99-cv-212429, 16th Cir. Ct. Jackson County, Missouri, complaint filed July 2, 1999, ((Missouri Attorney General sued to enjoin Texas based pharmacy from selling drugs to Missourians)); see also, Christie Appelhanz, *Stovall: Internet isn't a drug store*, TOPEKA CAPITAL JOURNAL, Jun. 10, 1999, available in WESTLAW at 1999 WL 20053473 (State v. Confirmed.com, No. 99-c-748, Kansas Dist. Ct., Topeka County, complaint filed Jun. 9, 1999, ((Kansas Attorney General announced lawsuits to enjoin several companies and doctors from practicing medicine in Kansas without first being properly licensed)); see generally, *supra* note 15.

³¹ See Doulin, *supra* note 15.

³² See *id.*

³³ See *id.*

³⁴ See *id.*; see also, *Ohio State Medical Board Administrative Rules, 4733-11-09(A)*, <<http://www.state.oh.us/med/rules/11-09.htm>> (visited Jun. 28, 2000) (States in pertinent part, subject to certain exceptions, "a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.").

³⁵ See *Ryan Sues to Protect Consumers Against Illegal Sales of Prescription Drugs Over the Internet*, *supra* note 15, (The lawsuits are based Consumer Protection Statutes as well as State Medical/Pharmacy Acts.).

³⁶ See *id.*

³⁷ See *Hearings*, *supra* note 7 (statement of Cynthia Culmo, the Texas Department of Health, and statement of the Carla Stovall, Attorney General, Kansas).

³⁸ See *id.*

³⁹ See *id.* (statement of Carla Stovall, Attorney General, Kansas).

⁴⁰ See *id.*

⁴¹ See *id.*

⁴² See *supra* note 15; See also, Christie Appelhanz, *Stovall: Internet isn't a drug store*, TOPEKA CAPITAL JOURNAL, June 10, 1999, Available in WESTLAW, at 1999 WL 20053473, (Vicki Schmidt, A Kansas Board Pharmacy member, commenting on the Kansas lawsuit said "There has to be a physician-patient relationship [before a doctor may issue a prescription to a patient never seen], and clicking on a mouse does not establish that."); See also, Controlled Substance Act, 21 U.S.C. § 102 (6) (the term "Controlled Substance" is defined as a "drug or other substance, or immediate precursor,

included in schedule I, II, III, IV, or V of part B of this title.).

⁴³ See, e.g., *Ohio State Medical Board Administrative Rules, 4733-11-09(A)*, *supra* note 34.

⁴⁴ See *supra* note 15, *Ryan Sues to Protect consumers Against Illegal Sales of Prescription Drugs Over the Internet*, available in LEXIS (The lawsuit alleges that defendants, by failing to disclose to Illinois residents that they were not properly licensed, violated Illinois' Consumer Fraud and Deceptive Business Practices Act.).

⁴⁵ See H.R. 2763 106th Cong. (1999).

⁴⁶ See 21 U.S.C. §§ 351 *et seq.*

⁴⁷ H.R. 2763 provides, in part:
§503B. Internet Sales of Prescription Drugs

(b) Requirements

(1) The site shall include a page that provides the following information:

- (A) The name of such person; the address of the principal place of business of the person with respect to sales of prescription drugs through the Internet; and the telephone number for such place of business.
- (B) Each State in which the person is authorized by law to dispense prescription drugs.
- (C) The name of each individual who serves as a pharmacist for purposes of the site, and each State in which the individual is authorized by law to dispense prescription drugs.
- (D) If the person provides for medical consultations through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations; and the type or types of health professions for which the individual holds such licenses or other authorizations

⁴⁸ See *id.*, Sec. B

⁴⁹ See 145 CONG. REC. E1754-04 (daily ed. Aug. 5, 1999) (statement of Rep. Waxman).

⁵⁰ See *id.*

⁵¹ See *id.*

⁵² This sentiment was alluded to in an interview of Rep. Klink (D-PA), an original sponsor of the bill, by Susan Dentzer of *The Newshour with Jim Leher*, (PBS television broadcast, Nov. 18, 1999).

⁵³ See *Hearings*, *supra* note 7 (statement of Carmen Catizone, Executive Director, National Association of Board Pharmacies).

⁵⁴ See *id.*; see also, <<http://www.nabp.net>> (visited Jun. 26, 2000) (for more information on NABP or VIPPS certification).

⁵⁵ See *VIPPS Inspector Training Course To Be Held During NABP's 96th Annual Meeting* <<http://www.nabp.net>> (visited Jun. 28, 2000).

⁵⁶ See Hearings *supra* note 53.

⁵⁷ *Id.*

⁵⁸ See, *Hearings, supra* note 7 (statement of William Razzouk, CEO, PlanetRx.com); See also, *First Internet Healthcare Summit Industry Coalition Created to Monitor Internet Pharmacies; New Patient Protection Initiatives Proposed*, PR Newswire, November 10, 1999, at Financial News, available in LEXIS, News Library, Most Recent 60 Days; See also, Chris Taylor, *How to Buy Prescriptions Online*, Time Magazine, November 22, 1999 (instructing consumers to look for the VIPPS seal before shopping); *But see*, Val Cardinale, *Combining Brick and On-line Pharmacies; Way to Go?*, Drug Topics, November 1, 1999, available in LEXIS, at News Group File, Most Recent 60 Days (not everyone believes VIPPS will be a panacea; James Smith, a senior v.p. of Eckerd Corp., one of the largest drug chains in country, views VIPPS as merely a "seal with no teeth." A representative from the National Community Pharmacists Association also expressed skepticism over VIPPS effectiveness, noting that it is only a voluntary system and that NABP is not an agency with the ability to regulate as "a national entity.")

⁵⁹ See Chris Taylor, *How to Buy Prescription Online*, TIME, Nov. 22, 1999, at 44, (so far, three sites have been awarded certification; www.drugstore.com, <http://planetrx.com>, and www.merck-medco.com. Fifteen other companies are awaiting approval.)

⁶⁰ See *Hearings, supra* note 7 (statement of Jodie Bernstein, Director of the Bureau of Consumer Protection, FTC) (arguing for legislation that would require web sites offering prescription drugs to disclose certain information).

⁶¹ See Sheryl Gay Stolberg, *Officials Struggle to Regulate On-Line Sale of Prescription Drugs*, N.Y. TIMES, Jul. 31, 1999, at A12.; see also, Letter from Rep. Waxman to Melinda K. Plaisier, Interim Associate Commissioner for Legislative Affairs, Food and Drug Administration (Mar. 25, 1999).

⁶² See *Hearings, supra* note 7 (statement of Ivan Fong, Assoc. Att'y Gen., U.S. Dep't Justice) (At the federal level, an online drug shop which provides prescription drugs without a prescription, would be in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. §331(a). For prescribing based sites, the issue is whether there has been a valid prescription under §353(b) of the same act.)

⁶³ See 21 U.S.C. §331 *et seq.*

⁶⁴ (Besides states' authority under state medical, pharmacy, and consumer protection acts, the Justice Dep't and the FDA also have jurisdiction under the FDCA, 21 U.S.C §331 *et seq.* The FTC has authority under The Deceptive and Unfair Practices Act, 15 U.S.C. §45.)

⁶⁵ See *supra* note 34 (Many state medical boards are now addressing the issue of dispensing prescriptions without first physically examining the patient).

⁶⁶ See *Hearings, supra* note 7 (statements of AMA and NABP); see also, *Hearings, supra* note 7 (statements of Justice Dep't and FDA) (In its testimony, the Justice Dep't stated that, based on the circumstances involved, there may be a violation of 21 U.S.C. § 353(b). In earlier cases, the Justice Dep't has argued that under that section a prescription is not "valid" when there is no "bona fide doctor-patient relationship." The AMA stated that online questionnaires can not substitute for a proper physical exam.).

⁶⁷ See Bill Bell Jr., *Officials Warn That Patients Are At Risk At Some Web Drugstores; Some Pharmacies Will Fill Prescriptions With Only An Electronic Consultation*, ST. LOUIS POST-DISPATCH, Nov. 7, 1999 at C2 (comment made by Kenneth Miles, an owner of a Prescribing Based web site).

⁶⁸ See *id.* (Mr. Miles also noted that filling prescriptions via the Internet is no different than what numerous doctors do at some point in their careers. That is, they authorize a prescription via the phone to someone they haven't examined. For example, a new patient, scheduled to come to a physician's office in a few days, might need medication until he or she can be seen.).

⁶⁹ See *supra*, note 5, *Your Friendly Neighborhood E-Drugstore*; see also, *Hearings, supra* note 7.

⁷⁰ See Carol Smith, *Prescriptions in Cyberspace; Virtual Pharmacies Hope To Tap Health Care Market*, SEATTLE POST-Intelligencer, Feb. 1, 1999 at D1, (Prescription drug market expected to hit over \$150 Billion over the next four years.).

⁷¹ See *Hearings, supra* note 7.

⁷² Christie Appelhanz, *Stovall: Internet isn't a drug store*, TOPEKA CAPITAL JOURNAL, Jun. 10, 1999, available in WESTLAW at 1999 WL 20053473.

⁷³ See *Hearings, supra* note 7 (statement of Dr. Janet Woodcock, Director, FDA)

⁷⁴ See *id.*

⁷⁵ See *Hearings, supra* note 7 (statement of Ivan Fong, Assoc. Atty Gen., U.S. Dep't Justice) (Often a foreign based online drug shop may be taken off the Internet with the help of an Internet Service Provider, on a tip from the Justice Dep't or FTC or FDA. The problem is that those very same sites will often reappear the next day under a different name and different address.).

⁷⁶ See *id.*

⁷⁷ See *id.*

⁷⁸ See *Information on Importation of Drugs; Prepared by the Division of Import Operations and Policy, FDA*, <<http://www.fda.gov/ora/compliance>>; see also, *Book on Importing Drugs is Misleading and Could Cause Harm*, available at FDA web site under "Search."

⁷⁹ *See id.*

⁸⁰ *See id.*

⁸¹ *See Hearings, supra* note 7 (This is the consensus reached by all witnesses at the Congressional Hearing).

⁸² *See, e.g.*, <<http://www.cyberdocs.com>> (some Prescribing Based sites such as this one offer video conferencing for patients. Other sites such as <<http://www.procareclinic.com>> offer a detailed online questionnaire and then contact the patient before filling a prescription).

⁸³ *See Hearings, supra* note 7 (statement of Rep. Fred Upton).

⁸⁴ *See Hearings, supra* note 7 (statement of Dr. Herman Abromowitz, Member Board of Trustees, American Medical Association) (The Federation of State Medical Boards, has also come to a similar conclusion.).

⁸⁵ *See Hearings, supra* note 7, (statement of Dr. Janet Woodcock, Director, FDA); *see also*, Shari Roan, *Your Friendly Neighborhood E-Drugstore; The New Online Pharmacies Offer Prompt, Hassle-Free Service, But Health Experts Worry That The Sites Also Pose Serious Potential For Misuse*, L.A. TIMES, Sep. 20, 1999 at S1.

⁸⁶ *See Hearings, supra* note 7 (statement of Bob Michel, private citizen).

⁸⁷ *See Hearings, supra* note 7 (statement of Ellen Yui, private citizen).

⁸⁸ *See id.*

⁸⁹ *See id.*