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A Regulatory Challenge

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Abstract

The Internet presents new regulatory challenges despite many benefits in the field of research, communication and commerce. Since pharmaceutical web sites are accessible world wide, concerns about illegal and fraudulent sale practices have been raised on the domestic and the international level. This paper explores different attempts at regulating Internet pharmacies, taking the United States of America, Europe and New Zealand as examples. Although focusing on national issues, the paper also discusses crucial regulatory issues on an international level. It acknowledges that it is not yet clear how international law should apply to Internet pharmacies. Existing regulations on the domestic and international level seem to lag behind recent developments of the Internet. The approaches of countries to prosecute foreign pharmaceutical web sites are dissatisfied and moreover, can be questioned concerning limited international jurisdiction. Traditional legislative mechanisms probably work too slowly to cope with the development of the online pharmacy business. However, the growing use of the Internet calls for international co-operation to find an adequate solution.

The text of this paper (excluding contents page, footnotes and annexures) comprises approximately 17,000 words.

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Appendix 1 Constitution For The United States of America – Commerce Clause

In recent years the Internet has become a valuable source of information,

Appendix 2 Directive 2000/31/EC of the European Parliament and of the Council (Directive on electronic commerce)

every service. The e-commerce business "is one of the fastest growing markets" today. Companies are selling their products over the Internet promising a better, faster and even cheaper service. Moreover, for many people, the Internet reflects freedom, allowing almost total anonymity and operating at hours to suit the user. It has become increasingly common to communicate and conduct business over the Internet. The number of users "is predicted to grow 977 million in 2005,"¹² "making the Internet a lucrative business to enter."¹³

In order to compete more successfully, many pharmacies have created their own web sites offering medical products and services online. "It is estimated that there are currently over 400 businesses operating on the Internet that dispense prescription drugs"¹⁴ and the business is rapidly growing. Many people welcome the unique opportunity to buy medicine online. "It is convenient to order pharmaceuticals over the Internet, especially for people who might have "difficulty going to a pharmacy to obtain needed medication."¹⁵ Other benefits often cited are lower costs and privacy. Indeed, on the Internet no one knows who you are and your

¹²William K. Carroll, "The Taming of E-Health: Assessing U.S. Jurisdiction Over Foreign and Domestic Websites" (2001) *West Virginia Law Review* (on-file).

¹³<http://www.international.westlaw.com/Research/Products/compnet/default.asp?WLN=1245R-2.042X-100&ML=WestlawInternational%20Site> last accessed 7 February 2001.

¹⁴Carroll, above.

¹⁵James M. Cahill, "Liability on the Internet: Prescription Drugs and the Virtual Pharmacy" (2000) *Winter Law Review* (on-file).

¹⁶<http://www.lets.com/online/medication/default.asp?WLN=1245R-2.042X-100&ML=WestlawInternational%20Site> last accessed 7 February 2001.

¹⁷James M. Ward and Howard L. Dorfman, "The Case Against Labeling in an Internet Age" (2001) *Food and Drug Law Journal* (on-file).

¹⁸<http://www.international.westlaw.com/Research/Products/compnet/default.asp?WLN=1245R-2.042X-100&ML=WestlawInternational%20Site> last accessed 7 February 2001.

¹⁹*Joint Fact Statement for the Deputy Attorney General, Department of Justice Before the Subcommittee on Oversight and Investigations, Committee on Commerce, Consumer Affairs, and Administration, U.S. House of Representatives Concerning the Sale of Prescription Drugs over the Internet on 20 July 1999* (on-file).

²⁰<http://www.lets.com/online/medication/default.asp?WLN=1245R-2.042X-100&ML=WestlawInternational%20Site> last accessed 7 February 2001.

I Introduction

In recent years the Internet has become a valuable source of information, an easy and fast communication tool and a new opportunity to access almost every service one can think of. With hundreds of web sites, the e-commerce business "is one of the fastest growing markets"¹ today. Companies are selling their products over the Internet promising a better, faster and even cheaper service. Moreover, for many people, the Internet reflects freedom, allowing almost total anonymity and operating at hours to suit the user. It has become increasingly common to communicate and conduct business over the Internet. The number of users "is predicted to grow 977 million in 2005,"² "making the Internet a lucrative business to enter."³

In order to compete more successfully, many pharmacies have created their own web sites offering medical products and services online. "It is estimated that there are currently over 400 businesses operating on the Internet that dispense prescription drugs"⁴ and the business is rapidly growing. Many people welcome the unique opportunity to buy medicine online. It is convenient to order pharmaceuticals over the Internet, especially for people who might have "difficulty going to a pharmacy to obtain needed medication."⁵ Other benefits often cited are lower costs and privacy. Indeed, on the Internet no one knows who you are and your

¹ Melissa K. Cantrell "The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites" (2001) West Virginia Law Review [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

² Cantrell, above.

³ Joanna M. Carlini "Liability on the Internet: Prescription Drugs and the Virtual Pharmacy" (2000) Whittier Law Review [on-line].
<http://www.lexis.com/research/retrieve/frames?_m=e7fb4d96ad7819a2c00a60c3bfff9b95&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLStk-ISIWk&_md5=ecfec75d774e1db179a272899a801205> (last accessed 7 February 2002).

⁴ James M. Wood and Howard L. Dorfman "Dot.Com Medicine-Labeling in an Internet Age" (2001) Food and Drug Law Journal [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁵ Ivan Fong *Statement for the Deputy Associate Attorney General Department of Justice Before the Subcommittee on Oversight and Investigations Committee on Commerce United States House of Representatives Concerning the sale of Prescription Drugs over the Internet on 30 July 1999* [on-line].
<<http://www.usdoj.gov/criminal/cybercrime/fong9907.htm>> (last accessed 7 February 2002).

consultation with an online pharmacist seems to be more private than in the pharmacy store. Undoubtedly, online pharmacies can be a great benefit and value for the health care in the 21st century, as long as pharmacists operate their business with an appropriate level of responsibility for the customer's health. However, the sale of medicine over the Internet raises many concerns. The current trouble is that anyone can create a health-related web site selling pharmaceuticals over the Internet. How do you know that the "pharmacist on the other end of the line is a properly licensed pharmacist"⁶ and that the medication you ordered are approved drugs "of the appropriate level of quality, potency and dosage?"⁷ There are "plenty of fraudulent or disreputable Internet pharmacies"⁸ selling illegal, unapproved medication to customers often without receiving a valid prescription. Due to the lack of regulations, such unsafe and unscrupulous online pharmacies are potentially harmful to the public's health and welfare.

Many countries such as the United States of America⁹ and New Zealand have taken different approaches to "ensure an adequate level of confidentiality and control over consumers' personal health information and unfair, deceptive and fraudulent trade practices."¹⁰ However, regulators seem to struggle when it comes to liability and criminal offences of online pharmacies operating from foreign web sites. Many issues need to be considered such as:

- which country or court has the jurisdiction over foreign Internet pharmacies;

⁶ Ross D. Silverman "Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards" (2000) American Journal of Law and Medicine [on-line]. <<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002).

⁷ Silverman, above.

⁸ The White House, Office of the Press Secretary, *The Clinton Administration Unveils New Initiative to Protect Consumers Buying Prescription Drug Products Over the Internet* (28 December 1999) [on-line].

<<http://clinton4.nara.gov/textonly/WH/New/html/19991229.html>> (last accessed 8 February 2002).

⁹ Hereinafter the United States.

¹⁰ Nicole A. Rothstein "Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada" (2001) Federal Communications Law Journal [on-line]. <<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002).

- is it “possible to be held legally responsible in a foreign court for content on a web site that is legal in the user’s home jurisdiction;”¹¹
- how can the online pharmacy business be regulated to ensure an adequate protection to those living within a country’s jurisdiction without restricting “beneficial pharmaceutical care activities”¹² or affecting “the online innovations that can enhance the appropriate use of medications and improve a patient’s quality of life.”¹³

The existing law seems to fail when dealing with online pharmacies. It is often unclear who has the authority to investigate or to prosecute potentially harmful web sites. Companies can easily bypass any safeguard¹⁴ and even if they are prosecuted for illegal action such as selling medication without a valid prescription, the penalties they face are inadequate compared to the potential risk for the public’s health. It seems that the current misuse of the Internet can only be met with internationally adopted standards and guidelines¹⁵ and the online pharmacies’ understanding to comply “with all applicable laws and regulations.”¹⁶

The paper discusses, in both the domestic and international context, the challenges of regulating online pharmacies. It explores, examines and analyses the existing law and regulations in the United States, New Zealand and Europe. It further examines the responses of the pharmacy industry,

¹¹ Asaad Siddiqi “Welcome to the City of Bytes? An Assessment of the Traditional Methods Employed in the International Application of Jurisdiction over Internet Activities- Including A Critique of Suggested Approaches” (2001) *New York International Law Review* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹² David B. Brushwood “Responsive Regulation of Internet Pharmacy Practice” (2001) *Annals of Health Law* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹³ Brushwood, above.

¹⁴ John Henkel “Buying Drugs Online: It’s Convenient and Private, But Beware of ‘Rogue Sites’” [on-line]. <http://www.fda.gov/fdac/features/2000/100_online.html> (last accessed 7 February 2002).

¹⁵ C. Baur and M.J. Deering *2001 Report to Congress on Telemedicine- Safety and Standards* (22 May 2001) [on-line].

<<http://telehealth.hrsa.gov/pubs/report2001/safety.htm>> (last accessed 7 February 2002).

¹⁶ Melissa K. Cantrell “The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites” (2001) *West Virginia Law Review* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

such as voluntary safeguards. Special focus is given to regulatory and legal issues concerning criminal liability, investigation and prosecution of domestic and foreign pharmacy web sites. Although Internet pharmacies also raise questions concerning civil liability and redress, these issues will not be part of the paper. Part II of the paper explains the different categories of online pharmacies and examines advantages and disadvantages of ordering pharmaceuticals over the Internet. Part III examines current legislation and recent action by the United States, New Zealand and Europe against domestic and foreign online pharmacies. It focuses on the authorities' attempt to regulate investigation, criminal prosecution and jurisdictional issues. It further explores whether online pharmacies can be prosecuted on an international level. Therefore, it examines briefly jurisdictional issues under international law principles and describes various approaches that address jurisdictional problems. The United States has a particular interest in regulating the online pharmacy industry and setting up international guidelines. This part therefore examines cases where United States courts¹⁷ assert jurisdiction over businesses operating from foreign web sites in order to protect the customer's rights. It further looks at the jurisdiction within the European Union which seems to be unique when it comes to prosecuting foreign companies, even online pharmacies, in domestic courts. Part IV explores several approaches taken by the pharmacy industry, governments and agencies which might be effective in regulating online pharmacies world wide. The paper finally concludes that the market for online health care is currently in great danger due to the lack of regulations on domestic and international level. Countries need to acknowledge that domestic provisions are not enough to guarantee the public's protection against illegal and dangerous pharmacy web sites. The inevitable increase of the e-commerce business calls for wide regulations that ensure a controlled sale of medication over the Internet in interest of the public's health and welfare.

¹⁷ Hereinafter US courts.

II Online Pharmacies

As the number of online pharmacies increased, it has become easier to seek medication over the Internet. The first step is to find and access a pharmacy web site. Then, it is usually just a matter of minutes to enter your personal information, such as name, address, medical history, credit card number, prescription and how the medication should be delivered. Online shopping is simple and convenient, no waiting in line at the pharmacy store, no uncomfortable conversation with the pharmacist. As great as the benefits of online pharmacies seem to be, there are always risks for the consumer. Although Internet pharmacies are a fast growing business, it still is not clear which practices are legal and which are illegal.

There are various types of online pharmacies. Some of them provide enormous benefits offering medication under the same circumstances and with the same responsibility to the customer as a pharmacy store does. However, there are many Internet pharmacies that practise an unfair and fraudulent business and do not seem to care about the consumer's health and welfare. This part introduces briefly the different groups of online pharmacies. It further examines the benefits and risks of the sale of medicine over the Internet. Due to the concerns recently raised, special focus will be given to domestic and foreign online pharmacy web sites which offer pharmaceuticals without a valid prescription.

A How Do Online Pharmacies Operate

Pharmacies sell their products over the Internet in several ways. Although all web sites require "the patient to set up a personal account by choosing a user name and password"¹⁸ based on personal information, the service offered is quite different. Online pharmacies can generally be divided into three basic categories.

¹⁸ Amy J. Oliver "Internet Pharmacies: Regulation of a Growing Industry" (2000) *Journal of Law, Medicine & Ethics* [on-line].
<<http://international.westlaw.com/Welcom/WestlawInternational/default.wl?RS=WLIN2>.

First, there are pharmacies which have established their own web site and "offer traditional pharmacy service."¹⁹ They are the least controversial because the consumer requires a valid "prescription from a licensed physician"²⁰ before ordering the medication. The prescription must be sent over to the pharmacy before pharmaceuticals are dispensed. It is the same procedure as when one orders medication in a pharmacy store. Although the actions of such online pharmacies seem to be legal and "responsible for assuring accuracy in their traditional dispensing role,"²¹ concerns are raised regarding an appropriate licence for such borderless business. Generally, pharmacies are licensed for each state or country they intend to do their business. On the Internet they operate world-wide without being licensed. Thus, due to the lack of regulations, there is a great risk to act illegally and breach the law.

The second type of online pharmacies requires that the consumer consults an online physician –often employed by the pharmacy– who prescribes the medication after reviewing "an online medical questionnaire which asks for the patient's health profile, current medication and medical history."²² Despite the fact that the consumer will be charged with an additional fee, such practice can be questioned. Although the questionnaires will be reviewed by a physician, concerns are raised that the physician "[seems] to be paying little attention to what the applicant/prescription

71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹⁹ David Mills "Cybermedicine: The Benefits and Risks of Purchasing Drugs over the Internet" (2000) *Journal of Technology Law & Policy* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁰ Ivan Fong *Statement for the Deputy Associate Attorney General Department of Justice Before the Subcommittee on Oversight and Investigations Committee on Commerce United States House of Representatives Concerning the sale of Prescription Drugs over the Internet on 30 July 1999* [on-line].
<<http://www.usdoj.gov/criminal/cybercrime/fong9907.htm>> (last accessed 7 February 2002).

²¹ David B. Brushwood "Responsive Regulation of Internet Pharmacy Practice" (2001) *Annals of Health Law* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²² Fong, above.

buyer types in the blanks."²³ Prescriptions are filled too fast without a proper physical examination or the advice to consult another physician for a second opinion. No matter how detailed an online questionnaire might be "without an actual face to face exam, warning signs which might easily be detected by touch, could go unnoticed, posing potential risk to the patient."²⁴ Moreover, it is unlikely that the online pharmacy and the physician offer their service from the same state where the patient lives in. The criticism seems to be justified and the debate about these highly controversial web sites will continue until appropriate guidelines are set up to regulate these type of online pharmacies.

The third category is the most controversial because the consumer can order medicine either without a valid prescription or an online physician consultation. Prescription drugs such as "Viagra, Propecia (for hair loss), Xenical (weight loss), Zyban (smoking cessation), Celebrex (arthritis treatment) and Preven (emergency contraception)"²⁵ are available to everyone who fills out an online formula, enters the credit card number and "[agrees] to a waiver of liability."²⁶ The risks for consumers who access these web sites are significantly high. Although a medical questionnaire needs to be filled out, the answers are "often made up of YES/NO check boxes [or] boxes that are pre-selected to the answer that helps the consumer get the prescription."²⁷ It is the consumer's responsibility "to keep abreast of any complications or danger from taking [the] drug."²⁸ Again, these online pharmacies do not seem to care about the consumer's health. Their

²³ Joanna M. Carlini "Liability on the Internet: Prescription Drugs and the Virtual Pharmacy" (2000) Whittier Law Review [on-line].
<http://www.lexis.com/research/retrieve/frames?_m=e7fb4d96ad7819a2c00a60c3bfff9b95&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLStk-1SIWk&_md5=ecfec75d774e1db179a272899a801205> (last accessed 7 February 2002).

²⁴ David Mills "Cybermedicine: The Benefits and Risks of Purchasing Drugs over the Internet" (2000) Journal of Technology Law & Policy [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁵ Carlini, above.

²⁶ Ross D. Silverman "Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards" (2000) American Journal of Law and Medicine [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁷ Silverman, above.

²⁸ Carlini, above.

willingness to sell, often potentially dangerous and unapproved medication without a valid prescription raises serious concerns about the quality and effectiveness of the sale of medicine over the Internet in general. Authorities are well aware that the lack of regulations make such questionable activities possible and "the [public's] health and welfare [should be] protected from unlicensed and inappropriate"²⁹ online pharmacies.

B The Benefits And Risks Of Online Pharmacies

A business as fast growing as the sale of medicine over the Internet results in many advantages and disadvantages. There is no doubt that online pharmacies can "benefit modern health care in numerous ways."³⁰ They can "provide consumers with a convenient, private way to obtain needed medications."³¹ Before pharmacies created web sites and offered their service online, many elderly people or those living in rural areas had to go to the pharmacy store to receive their weekly or monthly prescription medicaments. It was often burdensome and required some effort. Now the Internet offers new opportunities, not only to the elderly or people living in remote areas. It is easy to access pharmacy web sites, "[convenient] of being able to order and obtain prescription drugs online,"³² receive a service which was previously not available³³ and additionally "to gain knowledge

²⁹ Silverman, above.

³⁰ Kerry Toth Rost "Policing the "Wild West" World of Internet Pharmacies" (2000) Food and Drug Law Journal [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

³¹ U.S. Food and Drug Administration "Buying Medicines and Medical Products Online" [on-line]. <<http://www.fda.gov/oc/buyonline/faqs.html>> (last accessed 8 February 2002).

³² Ivan Fong *Statement for the Deputy Associate Attorney General Department of Justice Before the Subcommittee on Oversight and Investigations Committee on Commerce United States House of Representatives Concerning the sale of Prescription Drugs over the Internet on 30 July 1999* [on-line].
<<http://www.usdoj.gov/criminal/cybercrime/fong9907.htm>> (last accessed 7 February 2002).

³³ Ross D. Silverman "Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards" (2000) American Journal of Law and Medicine [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

about medical products.”³⁴ Many people appreciate the anonymity of ordering drugs online, receiving a discrete and uncomplicated service or of being able to consult a pharmacist via the Internet about their illness without feeling uncomfortable.

“Privacy is often lacking in a traditional pharmacy.”³⁵ There is usually more than one customer in the pharmacy store and many people do not feel comfortable “asking a pharmacist questions in front of other customers.”³⁶ Moreover, “the Internet transcends geopolitical boundaries and time zones, globalizing drug knowledge with great rapidity.”³⁷ Consumers are being able “to get exactly what they want.”³⁸ The variety of the online pharmacy service and the possibility to access even foreign web sites make it more “efficiently and economically [for the consumer] to obtain products and services.”³⁹ Because of the growing online pharmacy business, medication will be sold “at more affordable prices.”⁴⁰ Lower prices are, especially for the uninsured or people who cannot afford expensive medication, an incentive to order medicine over the Internet. Overall, greater convenience,

³⁴ Nicole A. Rothstein “Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada” (2001) *Federal Communications Law Journal* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

³⁵ Kerry Toth Rost “Policing the “Wild West” World of Internet Pharmacies” (2000) *Food and Drug Law Journal* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

³⁶ Toth Rost, above.

³⁷ Emile L. Loza “FDA Regulation of Internet Pharmaceutical Communications: Strategies For Improvement” (2000) *Food and Drug Law Journal* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

³⁸ Ross D. Silverman “Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards” (2000) *American Journal of Law and Medicine* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

³⁹ Sara E. Zeman “Regulation of Online Pharmacies: A Case for Cooperative Federalism” (2001) *Annals of Health Law* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁴⁰ U.S. Food and Drug Administration “Buying Medicines and Medical Products Online” [on-line]. <<http://www.fda.gov/oc/buyonline/faqs.html>> (last accessed 8 February 2002).

a fast “cost-effective pharmaceutical service,”⁴¹ privacy, home delivery, an increasing report of medical and pharmaceutical information on pharmacy web sites and “greater patient satisfaction”⁴² are “many societal benefits”⁴³ of online pharmacies. The advantages of Internet pharmacies hold “great promise for improving access to and quality of health care.”⁴⁴

However, the online pharmacy business and the consumers are being threatened by unscrupulous, fraudulent and illegal activities of some companies. Many concerns have been raised recently regarding the potential health risks to consumers. Disreputable Internet pharmacies have taken advantage of unclear regulations concerning the online sale of medicine and “the patient’s lack of knowledge and understanding.”⁴⁵ Authorities claim that “certain web sites are nothing more than scams, collecting credit cards and cash, but providing no products”⁴⁶ or “selling

⁴¹ Sean P. Haney “Pharmaceutical Dispensing in the “Wild West”: Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies” (2000) William and Mary Law Review [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁴² Emile L. Loza “FDA Regulation of Internet Pharmaceutical Communications: Strategies For Improvement” (2000) Food and Drug Law Journal [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁴³ Nicole A. Rothstein “Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada” (2001) Federal Communications Law Journal [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁴⁴ BBC News *Internet Health Costs More* (6 November 1998) [on-line].

<http://news.bbc.co.uk/1/hi/english/health/newsid_689000/689597.stm> (last accessed 8 February 2002).

⁴⁵ Ross D. Silverman “Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards” (2000) American Journal of Law and Medicine [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁴⁶ Ivan Fong *Statement for the Deputy Associate Attorney General Department of Justice Before the Subcommittee on Oversight and Investigations Committee on Commerce United States House of Representatives Concerning the sale of Prescription Drugs over the Internet on 30 July 1999* [on-line].

<<http://www.usdoj.gov/criminal/cybercrime/fong9907.htm>> (last accessed 7 February 2002).

unapproved drugs, or products making unproven claims regarding cancer treatment and miracle weight loss.⁴⁷

Consumers are used to trusting the pharmacist's information and advice about a medicament. Misleading drug information may cause irreparable harm to the consumer's health. By ordering medicine from a "fraudulent or disreputable Internet pharmacy"⁴⁸ consumers "place themselves at risk of drug-related injury"⁴⁹ and are at potential risk "for deadly reactions."⁵⁰ In many cases, the "drugs are mislabeled or counterfeit,"⁵¹ "improperly prepared or not appropriate for [the consumer's] condition"⁵² or even contaminated or unapproved. In other cases, online pharmacies "might contain unreliable or out-of-date prescription use and dosage instructions, [often] printed in a foreign language."⁵³ Consumers may underestimate the impact of buying medications over the Internet. Even if they believe that they know everything about the medicine, they "might receive counterfeit drugs that contain inactive ingredients, expired legitimate medications diverted to illegitimate sellers, or dangerous sub-potent or super-potent versions that were improperly manufactured."⁵⁴ Furthermore, "there is no

⁴⁷ Melissa K. Cantrell "The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites" (2001) West Virginia Law Review [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁴⁸ The White House, Office of the Press Secretary, *The Clinton Administration Unveils New Initiative to Protect Consumers Buying Prescription Drug Products Over the Internet* (28 December 1999) [on-line].
<<http://clinton4.nara.gov/textonly/WH/New/html/19991229.html>> (last accessed 8 February 2002).

⁴⁹ Sara E. Zeman "Regulation of Online Pharmacies: A Case for Cooperative Federalism" (2001) *Annals of Health Law* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁵⁰ Cantrell, above.

⁵¹ Ivan Fong *Statement for the Deputy Associate Attorney General Department of Justice Before the Subcommittee on Oversight and Investigations Committee on Commerce United States House of Representatives Concerning the sale of Prescription Drugs over the Internet on 30 July 1999* [on-line].
<<http://www.usdoj.gov/criminal/cybercrime/fong9907.htm>> (last accessed 7 February 2002).

⁵² Zeman, above.

⁵³ Kerry Toth Rost "Policing the "Wild West" World of Internet Pharmacies" (2000) *Food and Drug Law Journal* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁵⁴ Toth Rost, above.

guarantee that these products are developed or packed in a sanitary way,"⁵⁵ "stored under sub-standard conditions"⁵⁶ and that they do not "contain impure or unknown ingredients."⁵⁷ There are many opportunities for fraud and unfortunately, "there are always unscrupulous people who will take advantage of the situation."⁵⁸ Such fraudulent, illegal activities always result in serious health risks for the consumer. There are potential risks for adverse effects including "antibiotic resistance, allergic reactions or other serious side effects."⁵⁹ Despite serious risks for the consumer's own health, people might give medications to their children without consulting a physician. They might even start with "self-diagnosis and self-medication."⁶⁰ It is easier to fill out an online questionnaire than to wait for an appointment at the doctor. Unfortunately, most consumers underestimate their medical knowledge. Although medical or pharmaceutical information is available on the Internet, it "may be beyond the technical comprehension of the [person]."⁶¹

Indeed, there are many legitimate online pharmacies which offer the same traditional, legal service as pharmacy stores do and "ensure that the drugs prescribed are proper for the patient,"⁶² approved, "manufactured, packaged, transported [and] stored under sub-standard conditions."⁶³ How does one know whether an Internet pharmacy is not disreputable or fraudulent? Many pharmacy web sites claim that there is no risk in ordering medication over the Internet. They even provide an online consultation with a physician and at first sight it really does not seem to be dangerous for

⁵⁵ Melissa K. Cantrell "The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites" (2001) West Virginia Law Review [on-line]. <<http://international.westlaw.com/Welcomes/WestlawInternational/default.wl?RS=WLIN2.71&YR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002).

⁵⁶ Toth Rost, above.

⁵⁷ Toth Rost, above.

⁵⁸ Tyler Chin "When Physicians Say No to Cipro, Some People Turn to the Internet, Online Pharmacies Under Fire for Prescribing Antibiotics for Worried Stockpillers", AMNews staff. (5 November 2001) [on-line]. <http://www.ama-assn.org/sci-pubs/amnews/pick_01/prca0806.htm> (last accessed 7 February 2002).

⁵⁹ Chin, above.

⁶⁰ Toth Rost, above.

⁶¹ Toth Rost, above.

⁶² Anne Fawcett "Online Rx: Overseas Sources Can Slash the Cost of Drugs, But Experts Prescribe Healthy Doses of Caution" (2001) Atlanta Journal and Constitution [on-line]. <http://bernie.house.gov/documents/articles/2001-08-07-rx_drugs.asp> (last accessed 7 February 2002).

⁶³ Toth Rost, above.

oneself. However, there are many concerns. How does one know how good the physician is, how much experience he/she has or what his/her area of speciality is? It is easy to create a web site. No one knows who you are or what you are doing for living. How trustworthy is someone on the other end of the line?

An additional concern is the potential of drug abuse.⁶⁴ In many cases, consumers are able to order and receive drugs without a valid prescription and without consulting a physician first. As long as you have a credit card, you can order as many medications as you want to. Online pharmacies do not seem to care if the medication you ordered is enough to treat the illness. "The inappropriate use of medication, which results in an individual's loss of control over the use of a drug and continued use despite negative consequences, is a major problem in the United States."⁶⁵ Usually, addicted people would "obtain prescription drugs illegal through alternation, theft, or forgery."⁶⁶ Today, there is no need to do it that way. The sale of medicine over the Internet has opened new dimensions which also indicates an increasing misuse and abuse of drugs. It is hard to control such abusive action because it is easy for addictive people to bypass safeguards. The possibility that an addict orders unapproved or corrupted drugs makes the situation even worse because of a serious death risk. It is estimated that "two-third of all drug-related injuries and deaths involve prescription drugs"⁶⁷ and it is probable that the number will increase.

Despite the fraudulent, "incomplete, misleading [and] inaccurate"⁶⁸ online pharmacy service, there are also concerns about privacy and

⁶⁴ Fawcett, above.

⁶⁵ Eric M. Peterson "Doctoring Prescriptions: Federal Barriers to combating Prescription Drug Fraud Against Online Pharmacies in Washington" (2000) Washington Law Review [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁶⁶ Peterson, above.

⁶⁷ Peterson, above.

⁶⁸ Sean P. Haney "Pharmaceutical Dispensing in the "Wild West": Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies" (2000) William and Mary Law Review [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split>

confidential medical and personal information transmitted over the Internet. What exactly happens with medical and personal information during or after one orders medication online? How secure is the system of online pharmacies? Who else can access confidential information? Are privacy and security concerns justified? There is indeed a lack of privacy. Most pharmacy web sites do not comply with a minimum standard of privacy. Although many people still believe that the Internet is a place where one can remain anonymous, it happens that "offline personal health information has been used inappropriately, without their knowledge or consent."⁶⁹ Medical and personal information can be accessed by a third party "through the use of cookies and banner advertisement,"⁷⁰ which unquestionably constitutes "without disclosure or consent an invasion of privacy."⁷¹ In some cases, online pharmacies share consumers' "information with third-party business partners."⁷² Due to the lack of regulations "there is no guarantee that information will remain confidential when a business goes bankrupt or is sold or merged."⁷³ When you order medicine over the Internet you must be aware that you will not have control over your medical and personal information. This may lead to significant problems such as "confidentiality breaches and discrimination."⁷⁴ Imagine that insurance companies can access the pharmacy web site where you just filled out an online medical questionnaire. What if they refuse to give you an insurance policy because of the knowledge they have about your health situation?

[71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split](#)> (last accessed 7 February 2002).

⁶⁹ Janlori Goldman and Zoe Hudson "Virtually Exposed: Privacy and E-Health; Privacy Concerns are Keeping Consumers From Reaping the Full Benefit of Online Health Information" (2000) The People-to-People Health Foundation, Inc. [on-line] <http://www.lexis.com/research/retrieve/frames?_m=fad3ad7d53ac7b31095879582a09c4e1&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLSZV-1S1WS&_md5=706f28c59a44c186e582e91b2b906c74> (last accessed 7 February 2002).

⁷⁰ Goldman and Hudson, above.

⁷¹ Nicole A. Rothstein "Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada" (2001) Federal Communications Law Journal [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁷² Rothstein, above.

⁷³ Goldman and Hudson, above.

⁷⁴ Emile L. Loza "FDA Regulation of Internet Pharmaceutical Communications: Strategies For Improvement" (2000) Food and Drug Law Journal [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

The online pharmacy industry is so "fast growing that it is not clear which practices are legal and which are prohibited."⁷⁵ However, while thinking of an effective way to regulate Internet pharmacies, it is essential to be aware of the advantages and disadvantages and to weigh the benefits against the risks.

III Current Regulatory Issues

The growing widespread use of the Internet to sell medicine "presents new challenges [for] government regulators, consumers and the industry itself."⁷⁶ Traditionally, pharmacies were regulated by enacted law provisions such as pharmacy Acts. These regulations explicitly state principles pharmacies must comply with to ensure effective protection of the public's health. Unfortunately, "Internet pharmacies do not fit into the standard regulatory scheme."⁷⁷ A great number of online pharmacies do not meet the minimum standard of the existing regulations because "the Internet makes it easy to bypass safeguards."⁷⁸ Authorities have recognised the problems with the sale of medicine over the Internet, especially with fraudulent and disreputable online pharmacies. They are aware that it is not enough to warn consumers of the "danger of getting drugs over the Internet

⁷⁵ David Mills "Cybermedicine: The Benefits and Risks of Purchasing Drugs over the Internet" (2000) *Journal of Technology Law & Policy* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁷⁶ Bruce Merlin Fried, Gadi Weinreich, Gina M. Cavalier and Kathleen J. Lester "E-Health: Technologic Revolution Meets Regulatory Constraint; An Internet-Driven Health System Poses New Challenges for an Area Already Thick With Regulations" (2000) The People-to-People Health Foundation, Inc. [on-line].

<http://www.lexis.com/research/retrieve/frames?_m=fad3ad7d53ac7b31095879582a09c4e1&fmtstr=CITE&docnum=1&startdoc=1&startchk=&wchp=dGLSzV-ISIWS&_md5=706f28c59a44c186e582e91b2b906c74> (last accessed 7 February 2002).

⁷⁷ David B. Brushwood "Responsive Regulation of Internet Pharmacy Practice" (2001) *Annals of Health Law* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁷⁸ The White House, Office of the Press Secretary, *The Clinton Administration Unveils New Initiative to Protect Consumers Buying Prescription Drug Products Over the Internet* (28 December 1999) [on-line].

<<http://clinton4.nara.gov/textonly/WH/New/html/19991229.html>> (last accessed 8 February 2002).

and how inappropriate it is⁷⁹ and call for explicit regulations. They acknowledge that various “ways of conduction on Internet pharmacy business lead to differing needs of regulation to protect the public’s health”⁸⁰ while recognising the benefits of online pharmacies. While questions are raised about what can and should be done about online drug sale, it is obvious that “online pharmacies must maintain all necessary state pharmacy licenses, follow all appropriate pharmacy laws and other regulations.”⁸¹ Although some successful actions have already been taken, “new law will be needed to improve the current situation.”⁸²

next?

This part explores current domestic and international regulatory issues in the context of the United States, Europe and New Zealand. It starts with an examination of the United States’ domestic regulations, focusing on federal and state initiatives. It then refers to European regulations, focusing on principles of the movement of goods and the protection of health and human life by governments according to Article 28 and 30 ECT. This part also examines the current New Zealand law focusing on the attempt to regulate the sale of medicine over the Internet on the domestic level. Finally, the part addresses international regulatory issues focusing on jurisdictional problems due to the borderless online pharmacy business. It further explores how the United States as one of the leading countries addressing online pharmacy issues has dealt with problems concerning investigation, lawsuits and jurisdiction over foreign web sites. It also looks at possible approaches concerning Internet pharmacies on an international level, such as what role the World Health Organisation⁸³ and other nations play when it comes to international regulations of online pharmacies.

⁷⁹ BBC News *Internet Health Costs More* (29 September 1999) [on-line]. <http://news.bbc.co.uk/hi/english/health/newsid_461000/461070.stm> (last accessed 8 February 2002).

⁸⁰ Brushwood, above.

⁸¹ Ross D. Silverman “Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards” (2000) *American Journal of Law and Medicine* [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁸² John Henkel “Buying Drugs Online: It’s Convenient and Private, But Beware of ‘Rogue Sites’” [on-line]. <http://www.fda.gov/fdac/features/2000/100_online.html> (last accessed 7 February 2002).

A Domestic Regulatory Issues

Due to the illegal practice of online pharmacies and the increasing risk for the public's health and welfare, several countries have proposed to regulate the sale of medicine over the Internet. In addition to that some states have already "taken action against illegitimate online sellers of prescription drugs, assessed fines and contemplating stiffer penalties."⁸⁴ Authorities request regulations "to better define the boundaries of legitimate online practice"⁸⁵ as well as to improve benefits and reduce risks of online pharmacies. Many questions need to be considered. What exactly is regulated by the current law? Are the current enforcement actions effective and appropriate to minimise problems with online drug sale? Who has the authority to regulate, investigate and prosecute fraudulent, illegal pharmacy web sites? Domestic regulations of online pharmacies may be different in the United States, Europe and New Zealand. However, the goal is the same—adequate health protection.

1 The United States

The rapid growing of the online pharmacy industry has launched "contentious debates over how and to what extent [the consumer] should be protected in the health area."⁸⁶ Federal and state representatives began "to discuss regulation of Internet pharmacies and considered other issues relating to the sale of drugs over the Internet"⁸⁷ in April 1999. In addition, many agencies have set up working groups to discuss regulatory issues and

⁸³ Hereinafter WHO.

⁸⁴ U.S. Food and Drug Administration "Buying Medicines and Medical Products Online" [on-line]. <<http://www.fda.gov/oc/buyonline/faqs.html>> (last accessed 8 February 2002).

⁸⁵ U.S. Food and Drug Administration, above.

⁸⁶ Janlori Goldman and Zoe Hudson "Virtually Exposed: Privacy and E-Health; Privacy Concerns are Keeping Consumers From Reaping the Full Benefit of Online Health Information" (2000) The People-to-People Health Foundation, Inc. [on-line] http://www.lexis.com/research/retrieve/frames?_m=fad3ad7d53ac7b31095879582a09c4e1&_f_mtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLSZV-1S1WS&_md5=706f28c59a44c186e582e91b2b906c74 (last accessed 7 February 2002).

⁸⁷ Kerry Toth Rost "Policing the "Wild West" World of Internet Pharmacies" (2000) Food and Drug Law Journal [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

actions against illegal pharmacy web sites and have introduced guidelines relating to online drug sale. However, authorities still face several problems to regulate online pharmacies on a domestic level. Because of the government system in the United States, laws concerning the Internet and health care "must comply with both national and state laws."⁸⁸ This part focuses on both federal regulatory initiatives and state regulatory activities.

1.1 The Clinton Administration

The Clinton Administration was the first to propose "a new initiative to protect consumers from the illegal sale of pharmaceuticals over the Internet,"⁸⁹ developing "a general policy that includes support for industry self-regulation where possible, technology-neutral laws and regulations, and an appreciation of the Internet as an important medium... for commerce."⁹⁰ Although the draft regulation only covered a small area of online drug sale, the goal of the initiative was to "establish new Federal requirements for all Internet pharmacies to ensure that they comply with state and Federal law; create new civil penalties for the illegal sale of pharmaceuticals; give Federal agencies new authority to swiftly gather the information needed to prosecute offenders; expand Federal enforcement efforts; and launch a new public education campaign about the potential danger of buying prescription drugs online."⁹¹ To achieve this goal, the Clinton Administration included a budget of 10 million dollars.⁹² According to the plan, the Food and Drug Administration⁹³ would have the "authority to investigate, identify and prosecute web sites selling unapproved new drugs, counterfeit drugs or

⁸⁸ Nicole A. Rothstein "Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada" (2001) Federal Communications Law Journal [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁸⁹ The White House, Office of the Press Secretary, *The Clinton Administration Unveils New Initiative to Protect Consumers Buying Prescription Drug Products Over the Internet* (28 December 1999) [on-line].

<<http://clinton4.nara.gov/textonly/WH/New/html/19991229.html>> (last accessed 8 February 2002).

⁹⁰ Rothstein, above.

⁹¹ The White House, Office of the Press Secretary, above.

⁹² The White House, Office of the Press Secretary, above.

⁹³ Hereinafter FDA.

prescription drugs without a valid prescription or those which fraudulently market drugs.”⁹⁴ However, the plan was criticised especially regarding the expanse of the FDA authority. Critics were “reluctant to have the federal government regulate an area traditionally controlled by the states.”⁹⁵ Although this policy has helped to find a way of regulating the sale of medicine over the Internet, it certainly is only the very first step in the right direction. The Clinton Administration itself could not have been an effective tool to track down illegal online pharmacies. It is not extensive enough to cover all problems.

1.2 The Federal Food, Drug and Cosmetic Act⁹⁶

Despite the government’s attempt to regulate online pharmacies, several agencies have introduced their guidelines for the safe sale of medicine over the Internet and have already taken some actions to investigate and prosecute illegal web sites as far as they are authorised to do so.

One of these federal agencies is the FDA which “regulates the safety, effectiveness and manufacturing of pharmaceutical drugs, as well as a part of the prescribing process”⁹⁷ authorised under the FFDC Act. The FFDC Act “was enacted in 1938 to control the sale of drugs and to authorise only those that are safe and effective.”⁹⁸ It prohibits the illegal sale of prescription drugs without a valid prescription. The purpose was to ensure the patient’s health which might be at risk from the sale of unsafe,

⁹⁴ Amy J. Oliver “Internet Pharmacies: Regulation of a Growing Industry” (2000) *Journal of Law, Medicine & Ethics* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

⁹⁵ Oliver, above.

⁹⁶ Hereinafter FFDC Act.

⁹⁷ John Henkel “Buying Drugs Online: It’s Convenient and Private, But Beware of ‘Rogue Sites’” [on-line]. <http://www.fda.gov/fdac/features/2000/100_online.html> (last accessed 7 February 2002).

⁹⁸ Sean P. Haney “Pharmaceutical Dispensing in the “Wild West”: Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies” (2000) *William and Mary Law Review* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

unapproved or counterfeit pharmaceuticals or illegal practices of pharmacies.

Due to the lack of explicit regulations for online pharmacies operating from United States' territory, it seems to be appropriate that online pharmacies comply with the FFDC Act. Any sale of medicine over the Internet without a valid prescription would be a violation of the FFDC Act. Thus, every Internet pharmacy bypassing these safeguards needs to be prosecuted by the FDA. Although the FDA is authorised to take actions against these web sites, greater concerns have been raised regarding online pharmacies which employ physicians to review the consumer's online medical questionnaire and then prescribe the medication. The FFDC Act only prohibits the illegal sale of medicine without a valid prescription. Thus, one can argue that there is no violation of the FFDC Act. However, the FFDC Act was enacted when regulators never thought about another form of selling medicine than in a pharmacy store. At that time, to receive a valid prescription required an appointment with a physician, a physical examination and a legitimate physician-patient relationship. Can there be a doctor-patient relationship based on the reviewing of an online questionnaire and moreover, is the prescription valid according to the FFDC Act? "A physician-patient relationship is established when a patient knowingly seeks the assistance of a physician and the physician knowingly agrees to provide care to the patient."⁹⁹ According to that definition, an appointment with a physician operating over the Internet would be enough to create such relationship. However, courts have held that "there is no doctor-patient relationship without face to face communication."¹⁰⁰ Filling

⁹⁹ Kelly K. Gelein "Are Online Consultations a Prescription For Trouble? The Uncharted Waters Of Cybermedicine" (2000) Brooklyn Law Review [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹⁰⁰ Joanna M. Carlini "Liability on the Internet: Prescription Drugs and the Virtual Pharmacy" (2000) Whittier Law Review [on-line].
<http://www.lexis.com/research/retrieve/frames?_m=e7fb4d96ad7819a2c00a60c3bfff9b95&fmtstr=CITE&docnum=1&startdoc=1&startchk=&wchp=dGLStk-lSIWk&md5=ecfec75d774e1db179a272899a801205> (last accessed 7 February 2002). It should be mentioned that according to the "Medical Council guidelines for doctors using the Internet require the doctor and patient to have met on at least one occasion in a face-to-face consultation, and for the patient to be under the care of that doctor." See Pharmaceutical Society of New Zealand "Definition of Medicine" [on-line].
<<http://www.psnz.org.nz/Practice/Handbook/Medicines.htm>> (last accessed 4 May 2002).

out an online questionnaire does not provide "the same standard of care as a doctor who physically examines a patient."¹⁰¹ Due to the increasing use of the Internet, it will be necessary to redefine the doctor-patient relationship. One could argue that such a relationship could be seen in the online contract between the patient and the physician. It is questionable whether there is a contract between the parties in cases where the physician is employed by the online pharmacy to review online questionnaires. The contract might be more likely between the patient and the Internet pharmacy. The doctor's reviewing of the questionnaire might only be an additional service of the pharmacy to the consumer. Even if there would be an independent online consultation, a contract could only be seen in the clickwrap agreement. However, courts do not recognise such agreements as a valid contract. Following the courts' rulings concerning a physician-patient relationship, an Internet prescription based upon the review of an online questionnaire violates the FFDC Act. Every violation could end in a prosecution of physicians and online pharmacies. The FDA already has taken successful actions. Due to the continuous investigation of pharmacy web sites, the agency has "identified over 600 cases related to suspected illegal Internet sales, with the first Internet prosecution having been undertaken in 1994."¹⁰² In several cases, physicians were prosecuted for dispensing medications without a valid prescription or for prescribing and distributing anabolic steroids to athletes and entertainers."¹⁰³ The FDA also brought a charge against an Internet site owner for selling unapproved "bogus HIV test kits."¹⁰⁴ The web site was shut down and the operator sentenced to 5 years in prison. The shut down of web sites is one of the advantages if the FDA is involved in the investigation and prosecution, because the web site owner is

¹⁰¹ Carlini, above.

¹⁰² U.S. Food and Drug Administration, Statement (30 July 1999) *Enforcement of Existing Laws Regarding The Sale of Prescription Pharmaceuticals over the Internet* [on-line]. <<http://www.fda.gov/oc/buyonline/existlaws.html>> (last accessed 8 February 2002).

¹⁰³ Ivan Fong *Statement for the Deputy Associate Attorney General Department of Justice Before the Subcommittee on Oversight and Investigations Committee on Commerce United States House of Representatives Concerning the sale of Prescription Drugs over the Internet on 30 July 1999* [on-line]. <<http://www.usdoj.gov/criminal/cybercrime/fong9907.htm>> (last accessed 7 February 2002).

¹⁰⁴ Melissa K. Cantrell "The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites" (2001) *West Virginia Law Review* [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

out of business in all states.¹⁰⁵ Usually, states face difficulties to enforce their laws in other states and there would be no guarantee that the operator would not create a new web site in another state.

Although the FDA claims that “the investigation and the resulting charges demonstrate the FDA’s commitment and determination to protect Americans from unscrupulous operators of web sites that illegally prescribe, promote, and sell prescription drugs,”¹⁰⁶ it offers little guidance to online pharmacies. Currently, the FDA sends a warning letter to companies “informing them of criminal and civil penalties they can face”¹⁰⁷ if they sell unapproved drugs or medication without a valid prescription. The agency “has also contracted web site managers and asked for their voluntary cooperation in removing violative sites.”¹⁰⁸ The FDA further “added information to its web site in order to assist consumers in safely purchasing drugs over the Internet.”¹⁰⁹ Despite these actions, the FDA does not consider guidelines relating to regulations of Internet pharmacies. Even the Internet Drug Sale Action Plan only “[expands and improves] the agency’s ability to address illegal sale of drugs over the Internet.”¹¹⁰ The FDA argues that an effective and adequate regulation of online pharmacies should be addressed “by state regulatory boards or other appropriate agencies”¹¹¹ and “wants to use existing law to regulate Internet pharmacies, rather than

¹⁰⁵ John Henkel “Buying Drugs Online: It’s Convenient and Private, But Beware of ‘Rogue Sites’” [on-line]. <http://www.fda.gov/fdac/features/2000/100_online.html> (last accessed 7 February 2002).

¹⁰⁶ Cantrell, above.

¹⁰⁷ Cantrell, above.

¹⁰⁸ U.S. Food and Drug Administration, Statement (30 July 1999) *Enforcement of Existing Laws Regarding The Sale of Prescription Pharmaceuticals over the Internet* [on-line]. <<http://www.fda.gov/oc/buyonline/existlaws.html>> (last accessed 8 February 2002).

¹⁰⁹ Amy J. Oliver “Internet Pharmacies: Regulation of a Growing Industry” (2000) *Journal of Law, Medicine & Ethics* [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹¹⁰ Melissa K. Cantrell “The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites” (2001) *West Virginia Law Review* [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹¹¹ Kerry Toth Rost “Policing the “Wild West” World of Internet Pharmacies” (2000) *Food and Drug Law Journal* [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

proposing new legislation.”¹¹² The agency’s reserve “may complicate compliance efforts, leaving pharmaceutical companies vulnerable to greater tort liability and resulting in inconsistent and perhaps unrestrained Internet approaches.”¹¹³ As welcome as actions against illegal web sites for the protection of the public are, adequate suggestions about how to regulate online pharmacy activities would be more effective as the current situation would become clearer and Internet pharmacies could comply with explicit law provisions and replace themselves from the FDA’s target of investigation and prosecution.

1.3 The Federal Trade Commission Act¹¹⁴

Numerous cases have involved unfair and deceptive practices of Internet pharmacies which fall under the FTC Act. Many online pharmacies make “false or misleading claims about the products or services [they provide] or false statements about how the site collects and uses medical information about the consumer.”¹¹⁵ The FTC Act authorises the Federal Trade Commission¹¹⁶ to take actions against pharmaceutical web sites “jeopardizing the health and safety of consumers with outlandish promises and false hope.”¹¹⁷ The FTC, as well as the FDA, is concerned about the public’s health and “has also played a significant role in prosecuting unfair and deceptive acts and practices by e-health sites.”¹¹⁸ The FTC’s main

¹¹² Joanna M. Carlini “Liability on the Internet: Prescription Drugs and the Virtual Pharmacy” (2000) Whittier Law Review [on-line].
<http://www.lexis.com/research/retrieve/frames?_m=e7fb4d96ad7819a2c00a60c3bfff9b95&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLStk-LSIWk&_md5=ecfec75d774e1db179a272899a801205> (last accessed 7 February 2002).

¹¹³ Emile L. Loza “FDA Regulation of Internet Pharmaceutical Communications: Strategies For Improvement” (2000) Food and Drug Law Journal [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹¹⁴ Hereinafter FTC Act.

¹¹⁵ Federal State Commission *FTC Testify “Drugstores on the Net: The Benefits and Risks of Online Pharmacies; Testimony Outlines Law Enforcement Effort* (30 July 1999) [on-line]. <<http://www.ftc.gov/opa/1999/9907/pharma.htm>> (last accessed 8 February 2002).

¹¹⁶ Hereinafter FTC.

¹¹⁷ Federal State Commission “*Operation Cure.All*” *Wages New Battle in Ongoing War Against Internet Health Fraud* (14 June 2001) [on-line].
<<http://www.ftc.gov/opa/2001/06/cureall.htm>> (last accessed 8 February 2002).

¹¹⁸ Melissa K. Cantrell “The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites” (2001) West Virginia Law Review [on-line].

concern is the failure of online pharmacies to comply with privacy standards.¹¹⁹ These objectives are justified as many online pharmacies do not guarantee an effective protection of the consumer's personal and medical information. Indeed, in many cases, pharmaceutical web sites are accessed by third parties. The consumer has no control over what happens to personal confidential information. Any privacy violation falls under the FTC Act and can be charged by the FTC. The agency further prosecutes online pharmacies which advertise their medication as "safe and effective without disclosing their possible effects"¹²⁰ or sell prescription drugs to consumers who provide a prescription based on the physician's review of an online medical questionnaire. As reviewed above, the current law and courts do not recognise a physician-patient relationship based on online consultation. Thus, every pharmaceutical web site violates not only the FDCA Act but the FTC Act and can be prosecuted by either the FDA or the FTC. Furthermore, the FTC has extended its enforcement action target to web sites which "marketing a variety of devices, herbal products, and other dietary supplements to treat or cure cancer, HIV/AIDS, arthritis, hepatitis, Alzheimer's, diabetes and many other diseases."¹²¹ However, many aspects of online prescribing and dispensing of prescription drugs do not fall clearly within the agency's traditional scope of authority or expertise and have been the primary responsibility of other federal and state agencies."¹²² Although the authority of the FTC is limited, the agency does not stop looking for opportunities to support other federal and state authorities, to monitor web

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹¹⁹ Nicole A. Rothstein "Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada" (2001) Federal Communications Law Journal [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹²⁰ Ivan Fong *Statement for the Deputy Associate Attorney General Department of Justice Before the Subcommittee on Oversight and Investigations Committee on Commerce United States House of Representatives Concerning the sale of Prescription Drugs over the Internet on 30 July 1999* [on-line].

<<http://www.usdoj.gov/criminal/cybercrime/fong9907.htm>> (last accessed 7 February 2002).

¹²¹ Federal State Commission "Operation Cure.All" *Wages New Battle in Ongoing War Against Internet Health Fraud*" (14 June 2001) [on-line].

<<http://www.ftc.gov/opa/2001/06/cureall.htm>> (last accessed 8 February 2002).

¹²² Federal State Commission "Operation Cure.All" *Wages New Battle in Ongoing War Against Internet Health Fraud*", above.

sites, conduct investigations, educate "consumers and businesses about illegal practices and how to protect themselves from fraud and deception"¹²³ or encourage online pharmacies to set up guidelines for their businesses through self-regulation. Unfortunately, the FTC itself does not make any suggestion for online pharmacy regulations arguing that it "is a problem that knows no borders, and intergovernmental co-operation is essential."¹²⁴ The increasing growth of the online pharmacy business "presents significant technological and logistical challenges to the traditional state regulatory framework."¹²⁵ As with the FDA, the FTC obviously does not seek additional authority to address issues concerning the sale of drugs over the Internet but assures that it will support any effective regulation.

1.4 The Internet Pharmacy Consumer Protection Act 1999¹²⁶

The IPCP Act was proposed to amend the FFDC Act.¹²⁷ The purpose was an easy determination of who operates a business over the Internet.¹²⁸ Under the IPCP Act, the web site operator would need to "list the principal plan of business, as well as the name and address of any physician or pharmacist working for the site,"¹²⁹ and where they are licensed to practice.

¹²³ Bruce Merlin Fried, Gadi Weinreich, Gina M. Cavalier and Kathleen J. Lester "E-Health: Technologic Revolution Meets Regulatory Constraint; An Internet-Driven Health System Poses New Challenges for an Area Already Thick With Regulations" (2000) The People-to-People Health Foundation, Inc. [on-line].
<http://www.lexis.com/research/retrieve/frames?_m=fad3ad7d53ac7b31095879582a09c4e1&fmtstr=CITE&docnum=1&startdoc=1&startchk=&wchp=dGLSzV-ISIWS&md5=706f28c59a44c186e582e91b2b906c74> (last accessed 7 February 2002).

¹²⁴ Federal State Commission "Operation Cure.All" *Wages New Battle in Ongoing War Against Internet Health Fraud*, above.

¹²⁵ Federal State Commission *FTC Testify "Drugstores on the Net: The Benefits and Risks of Online Pharmacies; Testimony Outlines Law Enforcement Effort"* (30 July 1999) [on-line]. <<http://www.ftc.gov/opa/1999/9907/pharma.htm>> (last accessed 8 February 2002).

¹²⁶ Hereinafter IPCP Act.

¹²⁷ Sara E. Zeman "Regulation of Online Pharmacies: A Case for Cooperative Federalism" (2001) *Annals of Health Law* [on-line].
<<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002).

¹²⁸ Joanna M. Carlini "Liability on the Internet: Prescription Drugs and the Virtual Pharmacy" (2000) *Whittier Law Review* [on-line].
<http://www.lexis.com/research/retrieve/frames?_m=e7fb4d96ad7819a2c00a60c3bfff9b95&fmtstr=CITE&docnum=1&startdoc=1&startchk=&wchp=dGLStk-ISIWk&md5=ecfec75d774e1db179a272899a801205> (last accessed 7 February 2002).

¹²⁹ David Mills "Cybermedicine: The Benefits and Risks of Purchasing Drugs over the Internet" (2000) *Journal of Technology Law & Policy* [on-line].
<<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2>.

In addition, "the bill prohibited online pharmacies from dispensing prescription drugs unless the web site disclosed information about who is selling the drugs."¹³⁰ It further addressed who the authority to regulate web sites is. It authorised the FDA and "alternatively, individual states, if they have adequate procedures to regulate the online pharmacies that are being run from that state."¹³¹ Although it seems that the IPCP Act would have many advantages for the online pharmacy business, it was widely criticised. The proposed expansion of the FDA's authority was disapproved as the "existing regulatory powers would allow the agency to pursue more extensive measure without the need for new grants of authority."¹³² That would discourage states in setting up their own provisions to regulate online pharmacies.¹³³ Although it seems likely that fraudulent and illegal practices might be stopped or at least reduced, there would be no guarantee that all pharmaceutical web sites are operated by licensed pharmacists. In fact, to identify unlicensed sites would be more difficult. Who can say that the operator not only put the pharmacist's or physician's name on the web site? What can authorities do in these cases? Even if the operator would comply with all requirements of the IPCP Act, what impact would it have for the physician-patient relationship? Could such relationship be established just because the physician's name and license is visible for authorities? In the end the IPCP Act does nothing to facilitate the problems authorities face with the online pharmacy business. Despite of all these questions, it is most likely that the IPCP Act will not be endorsed because of the reluctance and criticism of the National Boards of Pharmacy¹³⁴ and the unlikely support of states for a "federal licensing system that would allow practitioners to bypass state licensing and encourage reliance upon the

71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹³⁰ Zeman, above.

¹³¹ Carlini, above.

¹³² Zeman, above.

¹³³ Carlini, above.

¹³⁴ David Mills "Cybermedicine: The Benefits and Risks of Purchasing Drugs over the Internet" (2000) *Journal of Technology Law & Policy* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

federal government as primary enforcer of quality of care and professional practice standards."¹³⁵

1.5 The American Medical Association¹³⁶

Recently, the AMA has considered online pharmacy issues and expressed its concerns about Internet prescribing but mainly about the "significant erosion of [the physician-patient] relationship through improper, unregulated online prescribing."¹³⁷ It especially criticised the online medical questionnaire as "below a minimum standard of medical care."¹³⁸ Despite the fact that some questions about medical history can go beyond the consumer's knowledge, without a physical examination serious medical problems can easily be overlooked. The AMA's position is that the physician must fulfil certain requirements to ensure a minimum standard of medical care and to establish a valid physician-patient relationship. Generally, there must be an examination to determine a clear diagnosis based on the patient's medical history to which the physician need to have access; there must be a conversation between the doctor and the patient discussing the treatment of the illness, alternative methods and determine the best course of treatment; the physician further must inform the patient about benefits and risks of prescription medication, discuss side effects and if necessary, the physician must provide additional information, treatment and follow-up visits to view the therapeutic outcome.¹³⁹ It is evident that

¹³⁵ Sara E. Zeman "Regulation of Online Pharmacies: A Case for Cooperative Federalism" (2001) *Annals of Health Law* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹³⁶ Hereinafter AMA.

¹³⁷ Sean P. Haney "Pharmaceutical Dispensing in the "Wild West": Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies" (2000) *William and Mary Law Review* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹³⁸ Haney, above.

¹³⁹ Joanna M. Carlini "Liability on the Internet: Prescription Drugs and the Virtual Pharmacy" (2000) *Whittier Law Review* [on-line].

<http://www.lexis.com/research/retrieve/frames?_m=e7fb4d96ad7819a2c00a60c3bfff9b95&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLStk-LSIWk&_md5=ecfec75d774e1db179a272899a801205> (last accessed 7 February 2002).

physicians employed by Internet pharmacies cannot fulfil these requirements. However, the AMA does not condemn online pharmacy businesses but suggested "strict limits on when Internet prescribing is appropriate."¹⁴⁰ For an appropriate safeguard, the AMA "recommended a six-point plan concerning its professional role in guiding the use of online prescribing and its co-operation with other organisations in cyberspace,"¹⁴¹ especially the AMA's concern about an adequate consumer protection and "its desire that state licensing boards act against improperly operating sites as well as practitioners."¹⁴² Despite these recommendations, the AMA also adopted guidelines to develop the physician-patient relationship. The e-health initiative of the AMA "allows physicians to build their own dynamic and personalised web site, putting information from the nation's leading medical societies and resources from their own practices at their patient's fingertips."¹⁴³ With its current policy, the AMA has acknowledged that the Internet provides a lot of news opportunities for medical care and that it can be an effective tool in the communication between physicians, pharmacists and patients. However, due to lack of explicit regulations, the AMA opposed every online pharmacy business which does not meet certain requirements and a minimum standard of medical care.

1.6 State Government Regulations

While online pharmacy regulations were only discussed on a federal level, state authorities face difficulties with online pharmacies because of the inability to regulate the business "with existing licensing and consumer protection regulation."¹⁴⁴ The licensing system for pharmacies is state-

¹⁴⁰ Ross D. Silverman "Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards" (2000) American Journal of Law and Medicine [online].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹⁴¹ Haney, above.

¹⁴² Haney, above.

¹⁴³ Tyler Chin "American Medical Association, News in brief" (26 November 2001) [online]. <http://www.ama-assn.org/sci-pubs/amnews/pick_01/tebf1126.htm> (last accessed 7 February 2002).

¹⁴⁴ Sean P. Haney "Pharmaceutical Dispensing in the "Wild West": Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies" (2000) William

based and some states already have enacted laws to regulate Internet pharmacies or tried to directly regulate web site operators.¹⁴⁵ For example, "Illinois passed legislation amending the state's mail order pharmacy law that will allow the state Department of Professional Regulation to establish rules and regulations pertaining to Internet pharmacies."¹⁴⁶ Many other states such as Arkansas or Indiana with pharmacy statutes, modified or expanded them because of the increasing concerns of the growing Internet business concerning the sale of medicine.¹⁴⁷ At the same time, states noticed the jurisdictional problem of Internet pharmacy industry. Every state could pass its own law to regulate pharmacies as long as there is a necessity to ensure an adequate protection of people who live in that state. Thus, the states' independent attempt to regulate online pharmacies causes some difficulties. Online pharmacy operators, pharmacists and physicians "would face 50 different variants of regulation."¹⁴⁸ Even if the physician's or pharmacist's licence for running the business would be valid in one state, it would be invalid in other states. Thus, any sale of medicine to consumers in another state than they are licensed to practise would violate the state law. Even if they would attempt to apply for another state's licence it "would have great difficulty complying with a multitude of state approaches."¹⁴⁹ Furthermore, states would with such regulation limit the commerce of the online pharmacy businesses. According to the Commerce Clause of the U.S. Constitution only "the Congress shall have Power...to regulate

and Mary Law Review [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹⁴⁵ Joanna M. Carlini "Liability on the Internet: Prescription Drugs and the Virtual Pharmacy" (2000) Whittier Law Review [on-line].

<http://www.lexis.com/research/retrieve/frames?_m=e7fb4d96ad7819a2c00a60c3bfff9b95&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLStk-ISIWk&_md5=ecfec75d774e1db179a272899a801205> (last accessed 7 February 2002).

¹⁴⁶ Ross D. Silverman "Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards" (2000) American Journal of Law and Medicine [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹⁴⁷ Haney, above.

¹⁴⁸ W. John Thomas "Click On This Link, Buy Two Aspirins, And Call Me In the Morning: A Critique of Online Medicine Financial Arrangements" (2001) Cornell Journal of Law and Public Policy [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

Commerce among the several states.”¹⁵⁰ This Clause limits, as the Supreme Court in *General Motors Corp. v Tracy* stated “the ability of states to impede the flow of interstate commerce and thereby impedes free private trade in the national market place.”¹⁵¹ Any state regulation concerning the online pharmacy industry must comply with that Clause. Currently, the states’ regulations seem to violate per se the Clause.¹⁵² However, it will be up to the Congress to address the conflict between the states’ attempt to find an effective regulation for the online business to ensure the public’s protection and the needs of commerce according to the Clause.

Despite these difficulties, states already have taken actions against pharmaceutical web sites, pharmacists and physicians for “violating state medicine and pharmacy licensing requirements and state consumer fraud laws.”¹⁵³ Ohio, for example, brought charges against pharmacists and physicians for “prescribing dangerous drugs over the Internet and not [establishing] a proper physician-patient relationship by failing to do appropriate physical examination, which is necessary under Ohio law before prescription drugs may be issued to new patients.”¹⁵⁴ Missouri prosecuted “online pharmacy sites based on their failure to confirm patient’s health information, reviewed through online consultations, prior to issuing prescription and dispensing drugs.”¹⁵⁵ Kansas indicted online pharmacies for “deceptive advertising and selling prescription drugs with little or no evaluation of consumer’s physical conditions.”¹⁵⁶ Many other states, such

¹⁴⁹ Thomas, above.

¹⁵⁰ Constitution for the United States of America, Commerce Clause, Article 1 Section 8 [on-line]. <http://www.constitution.org/constit_.htm> (last accessed 10 February 2002).

¹⁵¹ Thomas, above.

¹⁵² Thomas, above.

¹⁵³ Sara E. Zeman “Regulation of Online Pharmacies: A Case for Cooperative Federalism” (2001) *Annals of Health Law* [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹⁵⁴ David Mills “Cybermedicine: The Benefits and Risks of Purchasing Drugs over the Internet” (2000) *Journal of Technology Law & Policy* [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹⁵⁵ Zeman, above.

¹⁵⁶ Melissa K. Cantrell “The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites” (2001) *West Virginia Law Review* [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split>

as Illinois, West Virginia and Texas, also took actions against Internet pharmacies. They mainly based their prosecution on failure to "register with the appropriate authorities in order to lawfully conduct business in their state and fill prescription authored by physicians not licensed to practice medicine in their state."¹⁵⁷ Since there are no explicit regulations, these kinds of lawsuits are currently the only effective weapon states have in the combat with illegal pharmaceutical web sites. These actions are undoubtedly a great success for each of the states but they are unlikely a solution for the borderless online business. A convicted Internet pharmacy might withdraw its service from one state but still operate in other states. Adequate regulations to deal with jurisdictional or commercial problems are still needed in the United States. While states have begun to regulate online pharmacies, it is now the federal government's task to consider the issues more fully and set up effective and adequate law provisions valid for every online pharmacy operating from U.S. territory.

2 Europe

The fast expanding of the pharmaceutical Internet business throughout the world has also raised concerns among the Member states of the European Union.¹⁵⁸ Internet pharmacies were established in the Netherlands, Switzerland and the United Kingdom selling their products to domestic, overseas customers and to people living within the EU. While the most EU Member states, including Germany, prohibit on a domestic level the sale of medicine over the Internet, online pharmacies seem to be legal in accordance with current European law provisions. However, the EU does not have explicit regulations concerning the Internet pharmacy business, although certain provisions apply to online businesses or the sale of products over the Internet within the EU. EU regulators have primarily set

[71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split](#)> (last accessed 7 February 2002).

¹⁵⁷ Amy J. Oliver "Internet Pharmacies: Regulation of a Growing Industry" (2000) *Journal of Law, Medicine & Ethics* [on-line].

http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

¹⁵⁸ Hereinafter EU.

up provisions to regulate the European market trying to avoid any discrimination between the Member states. It is the Member states' obligation to ensure that their law provisions comply with EU regulations. They are not allowed to set up guidelines which would prevent someone accessing their market. However, due to the increasing online pharmacy business and the lack of new regulations, Member states have to face a new challenge to find an adequate solution which complies with EU law but also with their own policy related to the sale of medicine over the Internet.

Recently, the National Court of Frankfurt a.M. has been made reference to the European Court of Justice¹⁵⁹ for a preliminary ruling concerning the Dutch online pharmacy *0800DocMorris.com* which sells its products to German consumers. The sale of medicine over the Internet within the EU raises many crucial questions. Can the current EU regulations deal with the Internet business? Do Member states discriminate against online pharmacies while prohibiting the sale of medicine to their nationals? Do states with their strict law provisions violate the principle of free movement of goods under Article 28 of the Treaty of the European Community?¹⁶⁰ Do Member states have the right to set up such provisions to protect the individual's health? This part examines certain European regulations which seem to apply to online pharmacies. It further focuses on Germany's prohibition to sell medication over the Internet, several rulings of German courts regarding the Dutch online pharmacy and the above mentioned order to the ECJ for a preliminary ruling. In addition, the part also reviews previous judgments of the ECJ and examines the probably impact of them on the recent case.

¹⁵⁹ Hereinafter ECJ

¹⁶⁰ Hereinafter ECT.

2.1 Current European Law

Since “medicines are subject to very strict Community regulations,”¹⁶¹ the EU and especially its Member states are concerned about the impact of online pharmacies on the public’s health. Under the existing EU law, “medicine, whether it is produced in the Community or imported, may not be placed on the market of a Member state before completion of a very strict procedure to guarantee its quality, safety and effectiveness.”¹⁶² Although there are no explicit regulations concerning the Internet pharmaceutical business, when it comes to the sale of products over web sites within the EU, Article 28 and 30 of the ECT and the Directive 2000/31/EC (1) of the 8 June 2000¹⁶³ need to be looked at. Under Article 28 of the ECT, Member states are not allowed to set up regulations which “constitute a measure having equivalent effect to a quantitative restriction on imports.”¹⁶⁴ Member states’ regulations have to comply with the principle of the free movement of goods, as the ECJ stated in its remarkable judgment in *Procureur du Roi v Dassonville, S.A. ETS Fourcroy and S.A. Breuval et Cie, Civil Parties*.¹⁶⁵ In *Dassonville*, the ECJ held that “all trading rules enacted by Member states which are capable of hindering, directly or indirectly, actually or potentially, intra-community trade are to be considered as measures having an effect equivalent to quantitative restrictions.”¹⁶⁶ According to the so-called Dassonville formula, the prohibition of the sale of medicine over the Internet from one Member state to another would be unquestionably a measure having effect equivalent to a restriction of

¹⁶¹ Bangeman *European Union Parliamentary Questions, Subject: Sale of Medicine Over The Internet* [online].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&SV=Split&FN=_top&MT=WestlawInternation> (last accessed 7 February 2002).

¹⁶² Bangeman, above.

¹⁶³ Hereinafter Directive on electronic commerce or Directive.

¹⁶⁴ European Court of Justice, EU Case C-322/01, (2001) [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&SV=Split&FN=_top&MT=WestlawInternation> (last accessed 10 February 2002).

¹⁶⁵ Hereinafter *Dassonville*. See European Court of Justice *Procureur du Roi v Dassonville, S.A. ETS Fourcroy and S.A. Breuval et Cie, Civil Parties*, Judgment (11 July 1974) [on-line]

<http://web2.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLV2.72&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 10 February 2002).

¹⁶⁶ See European Court of Justice *Procureur du Roi v Dassonville, S.A. ETS Fourcroy and S.A. Breuval et Cie, Civil Parties*, above.

imports. However, the ECJ limited the range of application of Article 28 of the ECT in *Bernhard Keck and Daniel Mithouard*.¹⁶⁷ It stated that “the application to products from other Member states of national provision restricting or prohibiting certain selling arrangements is not such as hinder directly, indirectly, actually or potentially, trade between Member states within the meaning of Dassonville as long as those provisions apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member states.”¹⁶⁸ Thus, certain sales modifications in the Member state are not equivalent measures “and fall outside the scope of Article 30 [of the ECT].”¹⁶⁹ According to the *Keck and Mithouard* judgment, the prohibition of the sale of medicine over the Internet and thus, the import of such pharmaceuticals to the consumer is not a product-related and non-discriminating sale modality and does not violate Article 28 of the ECT.¹⁷⁰ The prohibition must apply to domestic and other Member states’ businesses. However, one also can argue that such prohibitions would make it impossible for Member states’ companies to access market of another Member state. Even if Article 28 of the ECT would be violated by a Member state’s import prohibition, it could be justified by Article 30 of the ECT.

Article 30 provides:

The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, ... Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member states.

¹⁶⁷ Hereinafter *Keck and Mithouard*. See European Court of Justice *Bernhard Keck and Daniel Mithouard*, Judgment (24 November 1993) [on-line] <<http://web2.westlaw.com/Welcom/WestlawInternational/default.wl?RS=WLW2.72&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 10 February 2002).

¹⁶⁸ European Court of Justice *Bernhard Keck and Daniel Mithouard*, above.

¹⁶⁹ European Court of Justice *Bernhard Keck and Daniel Mithouard*, above.

¹⁷⁰ The National Court of Frankfurt a.M., Judgment (9 November 2000), K&R 2001, 153, 157.

According to Article 30 each Member state can restrict its market by legal provisions if it is necessary for the protection of the health and life. Although the ECJ ruled that the health and the life of an individual is very important and it is up to the Member state to determine the extent of an adequate protection through regulations,¹⁷¹ it is unclear, due to the lack of explicit EU provisions, whether the ECJ would still uphold its ruling in cases of online pharmacies. While some Member states have already legalised the sale of medicine over the Internet,¹⁷² other Member states still keep up their policy in order to protect the public's health. However, Articles 28 and 30 of the ECT are the starting points when it comes to whether the sale of medicine to consumers living in Member states violates EU law.

While considering the online pharmacy business under EU regulations, one also needs to look at the Directive on electronic commerce. The purpose of that Directive is to ensure an adequate function of the EU market and to secure, under consideration of the principles of the freedom of establishment and the freedom of service, unlimited transmission of companies' services between the Member states.¹⁷³ Especially considerable is the so-called country of origin principle in accordance with Article 3 of the Directive. It provides that each Member state shall ensure that the information society service provided by a service provider established on its territory comply with the national provisions applicable in the Member state in question which fall within the co-ordinated field."¹⁷⁴ Thus, online pharmacies running their business from a Member state only have to comply with its regulation and could sell its product to other Member states even though these states would have prohibited such sale. However, it is not quite clear whether the sale of medicine over the Internet falls within that range of application. It could be argued that according to Article 2 (h) of

¹⁷¹ See the National Court of Frankfurt a.M., Judgment (9 November 2000), K&R 2001, 153, 157.

¹⁷² DocMorris is legalised and controlled by the Dutch Ministry of Health.

¹⁷³ Heinrich Hanika "Internetrecht Versus Schutz der oeffentlichen Gesundheit und Standesrecht", MedR 2000, 205.

¹⁷⁴ See Article 3 (1) of the Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market [on-line].

<<http://web2.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLW2.72&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 10 February 2002).

the Directive national demands concerning the supply of goods do not fall into the range of the Directive.¹⁷⁵ The Directive only concerns activities which are actually exercised electronically.¹⁷⁶ Only the contract over the sale of medicine would fall into the range of Article 3 of the Directive but not the delivery to the consumer. The consideration reason No. 21 to the Directive states that the requirements concerning the delivery of medicinal products does not fall into the co-ordinated range.¹⁷⁷ However, so far, only German courts have interpreted the Directive related to online pharmacy businesses. The interpretation of the ECJ is yet to come. Its ruling might clarify how courts should read and apply the Directive relating to Internet pharmacies.

2.2 Germany's Lawsuits Against *0800DocMorris.com*¹⁷⁸

The Dutch online pharmacy DocMorris, controlled by the Dutch ministry of health,¹⁷⁹ has been recently sued in German courts for violating the Gesetz zur Neuordnung des Arzneimittelrechts (the law making provision with respect to medicinal products) of 24 August 1976.¹⁸⁰ The sale of medicine over the Internet is strictly prohibited in Germany.¹⁸¹ DocMorris, however, sold and delivered via a delivery service medication to German consumers which violates section 43 I 1,2 of the AMG providing that the sale of medicine outside pharmacy stores and the trade of medications is prohibited. Thus, the delivery also is contrary to the AMG. Germany restricted the sale of medication to pharmacy stores to control the market ensuring that only approved and for the German pharmacy market licensed

¹⁷⁵ The National Court of Frankfurt a.M., Judgment (9 November 2000), K&R 2001, 153, 158.

¹⁷⁶ The National Court of Frankfurt a.M., above.

¹⁷⁷ The National Court of Frankfurt a.M., above. See also consideration point 21 of the Directive 2000/31/EC, above.

¹⁷⁸ Hereinafter DocMorris

¹⁷⁹ Anna M. Hoettecke "Wem nuetzt die Internet-Apotheke?" [on-line] <http://www.wdr.de/tv/service/geld/inhalte/010412_1.html> (last accessed 7 February 2002).

¹⁸⁰ Hereinafter AMG.

¹⁸¹ Kai Althoetmar and Markus Maier "Medikamente aus der Internet-Apotheke" [on-line]. <http://www.wdr.de/tv/markt/service/berichte/20010412_1phtml> (last accessed 7 February 2002).

medicine will be sold to patients. The purpose is to guarantee the public's health, the safety of medication¹⁸² and to avoid financial risks.¹⁸³

Although German law generally prohibits commerce with medicine outside pharmacy stores, courts decided differently about the DocMorris pharmacy. The National Court of Berlin ruled that the sale of medication over a Member state's web site does not violate the AMG. Section 73 II No. 6 (a) of the AMG explicitly states that consumers can, for personal needs, buy medicine in a Member state. The court further stated that a general prohibition for the sale of medicine to German consumers would obstruct the access to the German market through a Member state pharmacy.¹⁸⁴ Such prohibition is contrary to Article 28 of the ECT. It cannot be claimed that such provisions are justified for the public's health by Article 30 of the ECT.¹⁸⁵ The population's safety can also be guaranteed if the medicine is imported from a Member state's pharmacy. Furthermore, security measures would be less restrictive but could ensure an effective public's protection.¹⁸⁶ The judgment of the National Court of Berlin was a success for DocMorris. It also seemed to open the way to the Member state's markets for online pharmacies. However, the court can only decide cases within its jurisdiction. In other lawsuits, DocMorris has lost. The National Court of Frankfurt a.M. ruled that the sale of medicine over the Internet violates the AMG.¹⁸⁷ In the judges' opinion, section 73 II AMG is not applicable in that specific case. Although consumers are allowed to buy medicine in a Member state's pharmacy for their own use, DocMorris sells medication for profit. Such activities are not covered by section 73 II AMG.¹⁸⁸ Section 73 II No. 6 (a) AMG is an exceptional norm which

¹⁸² ABDA *Sieg für Arzneimittelsicherheit* [on-line].

<<http://www.abda.de/ABDA/artikel.html?ID=137>> (last accessed 7 February 2002).

¹⁸³ *Verbraucherverbände für Medikamentenverkauf per Mausklick im Internet* (13 December 2000) [on-line].

<http://www.netdokter.de/topic/Internetapotheker/urteil_gefuehlt.htm> (last accessed 7 February 2002).

¹⁸⁴ The National Court of Berlin, Judgment (7 November 2000), K&R 2001, 168, 170.

¹⁸⁵ The National Court of Berlin, above.

¹⁸⁶ The National Court of Berlin, above.

¹⁸⁷ The National Court of Frankfurt a.M., Judgment (9 November 2000), K&R 2001, 153.

It should be mentioned that the court also held that DocMorris violates the HWG and UWG. However, the main arguments considered there those of the AMG relating to the public's health. Therefore, I only refer to these provisions in the paper.

¹⁸⁸ The National Court of Frankfurt a.M., Judgment (9 November 2000), K&R 2001, 153, 156.

explicitly restricts its range of application to the sale of medicine for non-commercial purposes. If every case could be interpreted under that section, it would not be an exception anymore. Such an interpretation would also fail the legislator's intent to restrict the commercial sale of medicine.¹⁸⁹ The court further stated that such understanding of section 73 II AMG would lead to an unacceptable consequence of residence discrimination.¹⁹⁰ Despite the different interpretation of section 73 II AMG, the National Court of Frankfurt a.M. also ruled differently concerning a possible restriction to the German market for Member states' pharmacies in accordance with Article 28 and 30 of the ECT. While referring to judgments of the ECJ concerning *Dassonville* and *Keck and Mithouard*, the court stated that, although the German law provisions are measures of same effect as Article 28 of the ECT, they are justified by Article 30 of the ECT. The public's protection requires such prohibitions. The German restriction concerning the sale of medicine has the primary purpose of giving consumers the possibility of a personal and qualified consultation with a pharmacist.¹⁹¹ The sale of medicine over the Internet cannot ensure the same protection as the sale in a pharmacy store.¹⁹² Even if the online pharmacy would provide an online or telephone consultation with a pharmacist, it is possible that the consumer does not use that service because of the inconvenience of writing an email or dialling the phone number. The court further referred to other disadvantages of online pharmacies and held finally that, due to the protection of people in Germany, the sale of medicine over the Internet still needs to be prohibited. German law also applies to Member state pharmacies, especially since the Federal High Court and the Federal Administrative Court held that even German pharmacies are not allowed to sell medicine in other ways than in a pharmacy store.¹⁹³

Because of the different judgments concerning *DocMorris* and a probable conflict of the AMG and EU provisions, the National Court of Frankfurt a.M. has made reference to the ECJ for a preliminary ruling in the

¹⁸⁹ The National Court of Frankfurt a.M., above.

¹⁹⁰ The National Court of Frankfurt a.M., above.

¹⁹¹ The National Court of Frankfurt a.M., Judgment (9 November 2000), K&R 2001, 153, 157.

¹⁹² The National Court of Frankfurt a.M., above.

DocMorris case. The court's question concerns the infringement of the principle of free movement of goods under Article 28 of the ECT by national legislation and the interpretation of Article 30 of the ECT and the Directive on electronic commerce in relation to the Internet presentation of an EU Member state's pharmacy.¹⁹⁴ The ECJ's ruling is expected in July 2002. As long as there is no judgment, DocMorris and other online pharmacies operating from Member states might be prohibited from selling their pharmaceutical products to German consumers.

2.3 Previous Judgments of the ECJ

Although the legitimation of online pharmacies has not been considered by the ECJ, the court already had to decide about the sale of medicine to consumers living in other Member states. In *Schuhmacher v Hauptzollamt Frankfurt (Main-Ost)*, a German national bought, as a tourist in France, medicine which was mailed by the French pharmacy store to the consumer's address in Germany. However, the customs authorities "relying on the [AMG], rejected Schuhmacher's application to have the medicinal preparation released into free circulation, on the grounds that to do so would infringe the prohibition of imports laid down in that law."¹⁹⁵ The ECJ held that the sale and delivery of medicine into another Member state cannot be restricted by national provisions.¹⁹⁶ Such "prohibition of imports of medicinal preparations by a private individual is a measure having an effect equivalent to a restriction of imports."¹⁹⁷ Germany's arguments that "the prohibition in question must be accepted because it forms an integral part of the distribution system for pharmaceutical products; as such, it is the only

¹⁹³ ABDA *Sieg für Arzneimittelsicherheit* [on-line].

<<http://www.abda.de/ABDA/artikel.html?ID=137>> (last accessed 7 February 2002).

¹⁹⁴ Case C 322/01. The full text of the order will be reprinted at the end of the paper.

¹⁹⁵ European Court of Justice, Opinion Tesouro, *Heinz Schuhmacher v Hauptzollamt Frankfurt am Main-Ost* (26 January 1989). [on-line].

<http://www.lexis.com/research/retrieve/frames?_m=042aabad317067f20388dc1a759c119f&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLStk-LSIWk&_md5=460d62ef3bfc474c86f09da3b1adcde3> (last accessed 10 February 2002).

¹⁹⁶ European Court of Justice, *Heinz Schuhmacher v Hauptzollamt Frankfurt am Main-Ost* Judgment (7 March 1989) [on-line].

<http://web2.westlaw.com/Find/Default.wl?DB=4709&SerialNum=1989189471&FindType=g&AP=&RS=WLW2.72&VR=2.0&SP=&SV=Split&MT=WestlawInternational&FN=t op&RLT=CLID_FQRLT5241313> (last accessed 10 February 2002).

suitable way of muting the requirements of protection of health and could not be changed or replaced by alternative means of control,"¹⁹⁸ were rejected by the ECJ. Pharmaceutical products are "among the products to which the principle of free movement of goods applies."¹⁹⁹ National prohibitions are only justified under certain circumstances such as the protection of health. In *Schuhmacher v Hauptzollamt Frankfurt (Main-Ost)* "all the requirements concerning the protection of health have already been taken into account in the state of exportation and that must be sufficient for the state of importation since the medicinal preparation in question [was] authorised in both the Member states."²⁰⁰ Tesauro J explicitly stated in his opinion to the case that "the argument based on the alleged need to ensure that the sale of medicinal preparations should be controlled on the national market by the pharmacist of the Member state of importation is manifestly unfounded. Once the Member states recognise the professional qualifications of pharmacists of other Member states, they no longer have any basis for claiming, without contradicting themselves, that the health of their population must be protected by ensuring that pharmaceutical products are sold by their own pharmacists."²⁰¹

In *Commission of the European Community v the Federal Republic of Germany*, the ECJ once again held that consumers may, for their own use, buy medicine in EU Member states.²⁰² It stated that national restrictions on free movement of goods ensuring pharmacies and consumers are not justified due to the European provisions which regulate the requirements for becoming a pharmacist equally for all Member states.²⁰³ Thus, it must be assumed that each Member state has the same high standards relating to the population's health.

¹⁹⁷ European Court of Justice, Opinion Tesauro, above.

¹⁹⁸ European Court of Justice, Opinion Tesauro, above.

¹⁹⁹ European Court of Justice, Opinion Tesauro, above.

²⁰⁰ European Court of Justice, Opinion Tesauro, above.

²⁰¹ European Court of Justice, Opinion Tesauro, above.

²⁰² Alexander Eichler "Arzneimittel im Internet-Anmerkung zu LG Frankfurt a.M., Urteile vom 9. November 2000", K&R 2001, 144-149. See European Court of Justice *Commission of the European Community v the Federal Republic of Germany*, Judgment (13 March 1992) [on-line].

<http://www.lexis.com/research/retrieve/frames?_m=042aabad317067f20388dc1a759c119f&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLStk-LSIWk&_md5=460d62ef3bfc474c86f09da3b1adcde3> (last accessed 7 February 2002).

²⁰³ Eichler, above.

Although these two judgments only refer to the sale of medicine through pharmacy stores, they might be applicable to online pharmacies, especially in *DocMorris*. The DocMorris pharmacy is controlled and legalised by the Dutch ministry of health. Because of this, the ECJ could rule that the German law violates EU provisions and discriminates against Member states in restricting the pharmaceutical market only to German pharmacists. Section 43 I of the AMG could be viewed as a discriminating sale modification and thus, as a measure of the same effect, according to Article 28 of the ECT. Germany can hardly uphold its argument that the prohibition is necessary for the public's protection and thus, justified under Article 30 of the ECT. It is more likely that the ECJ will again reject such arguments in cases where the online pharmacy is controlled and legalised by the Member state and sells legal and approved products. Furthermore, the ECJ could hold that Germany did not amend its law in respect to the previous judgments relating to the sale of medicine. There are no health risks because of the strict EU health provisions which every Member state must comply with. As stated above, the Member states already acknowledged the professional qualifications of pharmacists educated in a Member state. In doing so, they also acknowledged the safety measures in pharmacy stores either operating over the Internet or traditionally in a store. However, there is still the question of how the ECJ would rule in cases where the online pharmacy is not legalised and controlled by the Member state. It can hardly be argued, with the previous judgments of the ECJ, that the sale of medicine over the Internet is safe. It is questionable whether the public's protection can be guaranteed. Due to the lack of explicit provisions, Member states may successfully argue that national prohibitions, at least for these pharmaceutical businesses, are required to ensure an adequate protection of the public according to Article 30 of the ECT. The ECJ's ruling in *DocMorris* is awaited by governments, agencies, online pharmacies and consumers. Until then, national approaches to regulate the Internet pharmacy business should be considered.

3 New Zealand

The Internet pharmacy business is also growing in New Zealand with approximately 30 Internet pharmacies.²⁰⁴ The Dunedin pharmacy www.onlinepharmacy.co.nz is one of New Zealand's online pharmacies providing service to customers.²⁰⁵ However, the sale of medicine over the Internet is restricted to consumers with a prescription written by a practitioner registered in New Zealand due to the legislation passed by the government in November 2000.

Regulation 44 C of the Medicines Amendment Regulations 2000 provides:

No export of prescription medicines for retail sale without New Zealand prescription-

- (1) No person may export a prescription medicine in the course or for the purpose of retail sale, otherwise than under a prescription given by a practitioner, a registered midwife, or a designated prescriber.
- (2) The meaning of retail sale in subclause (1) must be determined by reference to section 5 (2) of the Act.
- (3) Subclause (1) is intended to limit the sale and supply of prescription medicines pursuant to section 33 (b) of the Act.

Despite this restriction, there are still many issues which need to be considered. The key issue is whether a customer can buy pharmaceuticals from an overseas web site, without breaching the laws of that country, and have it sent to New Zealand. This part looks at New Zealand law provisions concerning the sale of medicine over the Internet. It further examines the case *Bell v Medsafe New Zealand Medicines and Medical Devices Safety*

²⁰⁴ See Russell McVeagh "The Internet and Medicine" [on-line]. <http://www.findlaw.co.nz/articles/The_Internet_and_Medicine.htm> (last accessed 3 April 2002).

²⁰⁵ See website of the Dunedin Pharmacy, [on-line]. <<http://www.onlinepharmacy.co.nz>> (last accessed 10 January 2002).

*Authority*²⁰⁶ where the sale of medicine over the Internet was addressed for the first time in a New Zealand court and which led to the restriction on selling pharmaceuticals to overseas customers. Finally, while looking at the current situation in New Zealand concerning the online pharmacy business, it considers to what extent the sale of medicine over the Internet is restricted to consumers in New Zealand and overseas.

3.1 *Bell v Medsafe New Zealand Medicines and Medical Devices Safety Authority*

Since the Internet was used by pharmacies to sell their products to online customers, courts have had to decide whether the sale is lawful or not. In 1999, the issue was raised in the District Court of Auckland. Mr. Bell, a qualified and registered pharmacist, had advertised and sold pharmaceuticals, including prescription medicine, over the Internet to overseas customers from 1993 onwards.²⁰⁷ In the same year, two officers detained 178 parcels at the New Zealand Post depot at the Auckland Airport. The parcels were despatched by Mr. Bell to private addresses in the United States and the United Kingdom containing various prescription medicine including Viagra, Xenical, Prosac and Propetia. He sold the pharmaceuticals without receiving a valid prescription. The officers seized the parcels at the Airport and a quantity of prescription medicine held in the Internet pharmacy basement. While Medsafe, a business unit of the Ministry of Health, argued that the sale of medicine was unlawful, Mr. Bell applied for the return of the medicine seized by the officers pursuant to s. 65 of the Medicines Act. He denied committing an offence under the Medicines Act. Medsafe, however, claimed that the sale of prescription medicine to customers living overseas without a valid prescription was unlawful under s. 18 (2) of the Medicines Act which provides that no person may sell by retail any prescription medicine otherwise than under a

²⁰⁶ District Court of Auckland *Bell v Medsafe New Zealand Medicines and Medical Devices Safety Authority*, Judgment (23 December 1999) [on-line].
<http://www.lexis.com/research/retrieve/frames?_m=0e1e9ccedbbbb20954e5ab51901917ad&_fmtstr=VKWIC&docnum=1&_startdoc=1&_startchk=1&wchp=dGLStV-ISllz&_md5=979850dbe3a57b080a4958ef0fba111c> (last accessed 10 February 2002).

prescription given by a practitioner, registered midwife, veterinarian, or designed prescriber. It is in the interest of public health and safety to restrict indiscriminate public access to medicines of this kind and that requires that they can be available only on a proper medical prescription. Medsafe maintained that the sale of such medicine within New Zealand otherwise than upon prescription is prohibited and s. 18 (2) also applies to the overseas sale of medicine. While considering the lawfulness of Mr. Bell's online pharmacy business under the Medicines Act, the court ordered the return of the seized pharmaceuticals on the basis that a loophole in the law allowed the export of medicine that could be legally sold in New Zealand whether pursuant to a prescription or otherwise according to s. 33 (b) of the Medicines Act.

S. 33 (b) provides:

Notwithstanding section 17 to 24 of this Act or anything in any licence, but subject to the other provisions of this Act and to any regulations made under this Act, --

(b) Any person may export, in the course or for the purpose of sale, any medicine that, at the time when it is exported, might lawfully be sold by a pharmacist to a person in New Zealand, whether pursuant to a prescription or otherwise.

Gittos DCJ stated that a fair reading of the plain words of s. 33 (b) shows that the provision authorises

“the export in the course of sale or for the purpose of sale of any medicine that may lawfully be sold by a pharmacist in New Zealand; this authority extends to ‘any person’ and is to be seen as being enacted for the purpose of enabling the export of medicines for commercial purposes to proceed without restriction, provided such medicines are of the kind that may be lawfully sold by a pharmacist within New Zealand, [and finally], the words ‘whether by

²⁰⁷ All facts are adopted from District Court of Auckland *Bell v Medsafe New Zealand Medicines and Medical Devices Safety Authority*, above.

prescription or otherwise` make it clear that prescription medicines are intended to be included within the categories of medicines to which s. 33 refers.”²⁰⁸

Although s. 18 (2) of the Medicines Act defines three restricted classes of medicine, namely, prescription medicines, restricted medicines and pharmacy only medicines “all of which may only be sold through a pharmacy,”²⁰⁹ s. 33 (b) cannot be interpreted differently. Thus, “no offence [was] committed against s. 18 (2) [because] the Internet sales of prescription medicines are all export sales to persons in the United States and the United Kingdom.”²¹⁰ The arguments that “s. 33 is permissive in character and is not in itself a penal section [and therefore] the words ‘might lawfully’ should be treated as referring not only to the nature of the medicine sold but also as to the manner of the sale in New Zealand”²¹¹ were also rejected by the court as the argument that restrictions are “in the interest of public health and safety”²¹² and “the legislative intent that prescription medicines are to be closely controlled.”²¹³ The court concluded that “it would be dangerous for the court to speculate upon such matters [and] that the general approach to statutory interpretation must now be informed by a consideration of s. 5 of the Interpretation Act 1999.”²¹⁴ Gittos DCJ stated that “the text is clear [and] the material does not disclose any contrary legislative purpose which would justify reading this provision down in the way that the respondent contends for. If the applicant’s property is to be subject to seizure on the basis that his trade involves, or will involve, a breach of s. 18 (2) of the Act notwithstanding the dispensation contained in s. 33, then his liability should

²⁰⁸ District Court of Auckland, Gittos DCJ *Bell v Medsafe New Zealand Medicines and Medical Devices Safety Authority*, Judgment (23 December 1999) [on-line].
<http://www.lexis.com/research/retrieve/frames?_m=0e1e9ccedbbb20954e5ab51901917ad&_fmtstr=VKWIC&docnum=1&_startdoc=1&_startchk=1&wchp=dGLStV-ISllz&_md5=979850dbe3a57b080a4958ef0fba111c> (last accessed 10 February 2002).

²⁰⁹ District Court of Auckland, Gittos DCJ, above.

²¹⁰ District Court of Auckland, Gittos DCJ, above.

²¹¹ District Court of Auckland *Bell v Medsafe New Zealand Medicines and Medical Devices Safety Authority*, Judgment (23 December 1999) [on-line].

<http://www.lexis.com/research/retrieve/frames?_m=0e1e9ccedbbb20954e5ab51901917ad&_fmtstr=VKWIC&docnum=1&_startdoc=1&_startchk=1&wchp=dGLStV-ISllz&_md5=979850dbe3a57b080a4958ef0fba111c> (last accessed 10 February 2002).

²¹² District Court of Auckland *Bell v Medsafe New Zealand Medicines and Medical Devices Safety Authority*, above.

²¹³ District Court of Auckland *Bell v Medsafe New Zealand Medicines and Medical Devices Safety Authority*, above.

²¹⁴ District Court of Auckland *Bell v Medsafe New Zealand Medicines and Medical Devices Safety Authority*, above.

be spelt out by clear words in the enactment.”²¹⁵ The court’s decision clearly did not refer to the consumer’s health which might have been at great risk by selling prescription medicine without a valid prescription. However, the judgment, due to the lack of an explicit restriction in the Medicines Act on selling pharmaceuticals over the Internet to overseas customers, cannot be criticised. The arguments of Medsafe concerning the interest in the public’s health and the controlled sale of prescription medicine are strong but cannot be considered as long as the law does not explicitly refer to such an intention. The significant outcome of the case however was that the Executive Council passed regulations prohibiting selling and sending prescription medicines to overseas customers. Regulation 44 C of the Medicines Amendment Regulations 2000 clarifies “the intent of s. 33 (b) of the Medicines Act in prohibiting the export of prescription medicines for retail sale without a New Zealand prescription.”²¹⁶ The regulation refers explicitly to prescription medicines which are defined as a medicine that is declared by regulation made under this Act or by a notice given under section 106 to be one that, except as may be permitted by regulations made under this Act, may be-

- (a) Sold by retail only under a prescription given by a practitioner, registered midwife, veterinarian, or a designated prescriber, and
- (b) Supplied in circumstances corresponding to retail sale only-
 - (i) under a prescription given by a practitioner, registered midwife, veterinarian, or designated prescriber; or
 - (ii) In accordance with a standing order; and
- (c) Administered only in accordance with-
 - (i) A prescription given by a practitioner, registered midwife, veterinarian, or designated prescriber; or
 - (ii) A standing order.

²¹⁵ District Court of Auckland, Gittos DCJ, above.

²¹⁶ Pharmaceutical Society of New Zealand “Definition of Medicines” [on-line].
<<http://www.psnz.org.nz/Practice/Handbook/Medicines.htm>> (last accessed 4 Mai 2002).
It should be mentioned that the sale of non-prescription medicines which require least control and may be sold from any retail outlet is not covered by the legislation.

A full list of prescription medicines can be found in Part I of the First Schedule of the Medicines Amendment Regulations 2000.²¹⁷ Due to the need of a prescription written by a practitioner registered in New Zealand,²¹⁸ any sale and export of prescription medicine in response to a request or prescription from an overseas physician or countersigned by a New Zealand physician would violate the law.²¹⁹ Every person who commits an offence against the Medicines Act would face prosecution which may result in imprisonment or a fine.

S. 18 (5) and (6) provide:

- (5) Every person who sells or supplies or distributes a prescription medicine in contravention of subsection (1) of this section commits an offence and is liable imprisonment for a term not exceeding 6 months or a fine not exceeding \$ 1000.
- (6) Every person commits an offence against this Act who contravenes any of the provisions of this section (otherwise than in circumstances that constitute an offence against subsection (5) of this section).

Although the export sale of prescription medicines without a valid prescription is now prohibited, the Internet pharmacy business is still growing. It seems, however, that online pharmacies follow government regulation and have stopped selling their products to overseas customers.²²⁰ Some of them explicitly refer to the government restriction on their web sites to notify foreign consumers. The online pharmacy www.chemist.co.nz,

²¹⁷ The classification of any medicine can also be found on the Ministry of Health Medsafe web site <http://www.medsafe.govt.nz>. It should be noted that subsequent changes are notified in the New Zealand Gazette due to s. 106 of the Medicines Act.

²¹⁸ Any prescription must meet the legal requirements set out in the Medicines Regulations 1984 – s. 39-44 and 57.

²¹⁹ See Pharmaceutical Society of New Zealand, above.

²²⁰ See web site of the Dunedin online pharmacy where it is explicitly stated that „Following legislation passed by the New Zealand Government on 11th November 2000, we are prohibited sending Prescription Medicines to overseas customers.” [on-line]. <<http://www.onlinepharmacy.co.nz>> (last accessed 10 January 2002).

for example, states that "legislation prohibits New Zealand pharmacies from supplying prescription medicines offshore."²²¹

In addition to the legislation, the Medical Council has introduced guidelines for pharmacies selling their products over the Internet. They provide:²²²

- The same laws apply to a pharmacy internet site as to a pharmacy.
- The physical address of the site (that is the point from which medicines are sent) must be a registered pharmacy.
- The preparation and delivery of the medicines must be under the control and supervision of a pharmacist.
- If selling a pharmacist only (restricted) medicine, the pharmacist must be satisfied that the medicine is appropriate for the purchaser.
- Prescription medicines may only be supplied against a prescription written by a practitioner (doctor) registered in New Zealand.
- Prescription medicines may not be exported except to send a medicine prescribed by a New Zealand registered doctor to an overseas address.²²³

While ensuring an appropriate sale of prescription medicines, the legislation and guidelines seem to be adequate to protect consumers from risks associated with these medicines.

²²¹ See web site of the pharmacy <<http://www.chemist.co.nz>> (last accessed 10 February 2002).

²²² The guidelines are adopted from the web site of the Pharmaceutical Society of New Zealand "Definition of Medicines" [on-line]. <<http://www.psnz.org.nz/Practice/Handbook/Medicines.htm>> (last accessed 4 Mai 2002).

²²³ It should be mentioned that due to the Medical Council guidelines for doctors using the Internet require the doctor and patient to have met on at least one occasion in a face-to-face consultation, and for the patient to be under the care of that doctor. See Pharmaceutical Society of New Zealand, above.

3.2 The Current Online Pharmacy Business

Even with a regulation concerning the sale of medicine to overseas customers, there still is the question whether a New Zealand citizen can buy pharmaceuticals from a foreign online pharmacy without breaching the law of that country and have it sent to New Zealand? This issue has not been considered by the government or courts yet. There also is no explicit regulation prohibiting the purchase of pharmaceuticals from overseas web sites. At first sight, it seems that ordering and receiving drugs from foreign Internet pharmacies would be possible. However, it is most likely that the parcel containing the medication will be detected at customs. In that case, one could be accused of committing an offence according to the Misuse of Drugs Act.²²⁴ The MD Act prohibits, under heavy penalties, the import of medicine.

S. 6 (1) (a) of the MD Act provides

- (1) Except as provided in section 8 of this Act, or pursuant to a licence under this Act, or as otherwise permitted by regulations made under this Act, no person shall—
 - (a) Import into or export from New Zealand any controlled drug, other than a controlled drug specified or described in Part VI of the Third Schedule to this Act; or ...
- (2) Every person who contravenes subsection (1) of this section commits an offence against this Act and is liable on conviction on indictment to—
 - (a) Imprisonment for life where a Class A controlled drug was the controlled drug or one of the controlled drugs in relation to which the offence was committed:

²²⁴ Hereinafter MDAct.

- (b) Imprisonment for a term not exceeding 14 years where paragraph (a) of this subsection does not apply but a Class B controlled drug was the controlled drug or one of the controlled drugs in relation to which the offence was committed:
- (c) Imprisonment for a term not exceeding 8 years in any other case.

Controlled drugs means any substance, preparation, mixture, or article specified or described in the First Schedule, the Second Schedule, or the Third Schedule to this Act; and includes any controlled drug analogue. Thus, several pharmaceutical fall within s. 6 of the MD Act due to the chemical substances they consist of.

While the MD Act only applies to the import of controlled drugs, any order of prescription medicine will be covered by s. 43 of the Medicines Act.

S. 43 provides

- (1) No person shall, without reasonable excuse, import, procure, receive, store, use or otherwise have in his possession, any prescription medicine.
- (2) Without limiting the meaning of the expression "reasonable excuse" in subsection (1), a person has a reasonable excuse for the purpose of that subsection if-
 - (a) The possession or act that might otherwise be a contravention of that subsection-
 - (i) Is that of a person, licensed or otherwise authorised under this Act or any regulations made under this Act, to manufacture, sell, supply, pack, or administer the medicine or to be in possession of it; and

- (ii) Is necessary or incidental to the business, calling, or purpose for which the person is so licensed or otherwise authorised; or
- (b) The possession or act that might otherwise be a contravention of that subsection-
 - (i) Is that of a carrier, or an employee of a carrier; and
 - (ii) Is necessary or incidental to the business of that carrier; or
- (c) The possession or act that might otherwise be a contravention of that subsection-
 - (i) Is that of a person to whom the medicine has been lawfully supplied for his or her use, or for use by any other person, as a patient under the care of an authorised prescriber or in accordance with a standing order, and who does not have in his or her possession any other supplies of a prescription medicine prescribed or supplied for the same purpose by another authorised prescriber or in accordance with a standing order; and
 - (ii) Is necessary or incidental to such use; or
- (d) The possession or act that might otherwise be a contravention of that subsection-
 - (i) Is that of a person who has possession of the medicine only for the purpose of administering it to the person for whom it has been prescribed; and
 - (ii) Is necessary or incidental to that purpose; or
- (e) The possession or act that might otherwise be a contravention of that subsection-
 - (i) Is that of a person in the service of the Crown; and
 - (ii) Is necessary or incidental to the performance of that person's duties.

- (5) Every Person commits an offence against this Act who contravenes subsection (1) of this section.

S. 43 does not apply to the import of pharmacy only medicine and restricted medicine. The text of the section is clear and very specific. It cannot be argued that a person commits an offence and is liable for importing such medicine if s. 43 does not refer to the liability clear by words.

Due to these regulations, it seems that everyone who orders and receives prescription pharmaceuticals from a foreign web site breaches New Zealand law. Although the purchase itself does not violate the law, the import of medicine does. Thus, under the current New Zealand legislation, both the export and the import of prescription medicines are prohibited.

With such regulations, New Zealand tries to ensure that the pharmacy market is restricted to New Zealand controlled medicine and that the consumer's health and safety are protected from any risk of the Internet pharmacy business. Unfortunately, at present it cannot be said how effective the import and export prohibitions are. There will always be cases undiscovered by the customs and thus, without consequences. Currently, the regulation seems to be adequate to deal with the sale of medicine from overseas. Foreign Internet pharmacies seem to be, as a matter of fact, excluded from the New Zealand market. Who would buy pharmaceuticals overseas, if one commits an offence? However, the development of the growing borderless online pharmacy business will be interesting to watch. It is most likely that this business brings new challenges for the legislation in the coming years.

B International Regulatory Issues

As online pharmacy web sites continue to develop, the business will have a great value for consumers but also "face new exposure to out-of-[country]litigation and regulation."²²⁵ At present, Internet pharmacies have become targets of critique such as "the vast majority of the companies are not following the law."²²⁶ Special concerns have been raised about foreign pharmacies advertising and selling medicine without a valid prescription "including experimental or unapproved drugs not yet available in [many countries]."²²⁷ Authorities are aware that many people have bought such pharmaceuticals, risking their life, in foreign Internet pharmacies for years. However, they struggle to sue fraudulent and illegal online businesses for violating the law. In many cases, it is almost impossible to monitor web sites. As research showed, "only 10.7 % of the web sites would reveal their geographic location (city and country) beyond the information already posted on the web site."²²⁸ Even if the web site could be located, authorities have to face jurisdictional problems. While the Internet is a convenient way to order medicine from all over the world, it is difficult for authorities "to extend their jurisdiction over Internet conduct that has effects within their territory."²²⁹ Many crucial issues need to be considered when it comes to tracking down and prosecuting fraudulent and illegal online pharmacies. If it is illegal for a foreign pharmacy to ship prescription or unapproved medicine into another country, can the company be within reach of the regulatory arm of the other country? Can a country bring actions against a foreign web site and if so, where to file the lawsuit? Is it possible to enforce

²²⁵ eHealth Law Issues [on-line]. <<http://www.ehealthlawtoday.com/issues/content.shtml>> (last accessed 8 February 2002).

²²⁶ Carla J. Stovall *Before the Health, Education, Labor, & Pensions Committee; E-drugs: Who regulates Internet Pharmacies-Testimony* (21 March 2000) [on-line]. <<http://www.senate.gov/-labor/hearings/mar00hr/032100wt/stovall/stovall.htm>> (last accessed 7 February 2002).

²²⁷ Joanna M. Carlini "Liability on the Internet: Prescription Drugs and the Virtual Pharmacy" (2000) *Whittier Law Review* [on-line]. <http://www.lexis.com/research/retrieve/frames?_m=e7fb4d96ad7819a2c00a60c3bfff9b95&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLStk-LSIWk&_md5=ecfec75d774e1db179a272899a801205> (last accessed 7 February 2002).

²²⁸ Carlini, above.

²²⁹ Melissa K. Cantrell "The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites" (2001) *West Virginia Law Review* [on-line]. <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2_71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

a court's decision in another country? Should Internet pharmacies be regulated on an international level and if so, who should have the authority to do so? The key issue is how to overcome geographical and political boundaries to find an adequate solution in this subject matter?

International law was developed and enforced before the online pharmacy business started to develop. Traditionally, a country's jurisdiction is limited. However, since the borderless Internet business is growing rapidly, countries seem to become more and more interested in regulating such business and to extend their prescriptive jurisdiction. This part addresses jurisdictional conflicts authorities have to face with foreign based pharmacy web sites. It briefly surveys the traditional bases of international jurisdiction and whether and to what extent the current international law allows a country to take "jurisdiction of another sovereign based solely upon Internet activities."²³⁰ It then looks at a few cases on foreign defendants and Internet jurisdiction considered in the United States. It finally discusses criteria which might enable a country to prescribe rules for Internet pharmacies and to sue foreign companies in domestic courts.

1 Jurisdiction Under International Law

When it comes to jurisdictional matters concerning activities in a country's territory, it is usually up to the country how to deal with such matters. The country has often established explicit regulations stating in which jurisdiction the committed act falls. Jurisdiction is more important than any court's judgment, as good as it may be, because the ruling would be void if the subject matter does not fall within the court's range to decide it. Thus, a court can only claim jurisdiction in an international based lawsuit in accordance with international law provisions. International law, "well

²³⁰ Asaad Siddiqi "Welcome to the City of Bytes? An Assessment of the Traditional Methods Employed in the International Application of Jurisdiction over Internet Activities-Including A Critique of Suggested Approaches" (2001) New York International Law Review [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

developed in the twentieth century,²³¹ limits the extent to which a country has jurisdiction over another country's nationals due to the principles of "comity and the sovereign equality of nations."²³² Every country has to respect the other country's sovereignty and "has an obligation to exercise moderation and restraint in invoking jurisdiction over cases that have a foreign element, and should avoid undue encroachment on the jurisdiction of other sovereigns."²³³

The most common traditional bases for jurisdiction on an international level are the territoriality principle and the nationality principle. Following the territoriality principle, every country "is sovereign with respect to its territory and has the power, within its own territory, to prescribe and to proscribe activities of persons within its territory, whether or not such persons are nationals of that state."²³⁴ Under international law, a state is responsible for all "unlawful activities directed against other states."²³⁵ Although "this principle would allow a state to order service providers who operate on its territory to obey its regulation,"²³⁶ it is questionable if it applies "to control activities which happen in their territory [but] are not limited to the national territory."²³⁷ Unfortunately, the territoriality principle is not applicable when it comes to a foreign based Internet pharmacy because they run their business from another country's territory. Even if they do not comply with their own country's law, a foreign country cannot sue them for that action.

The nationality principle gives a country the power to "determine who its nationals are, [to] control their rights and responsibilities and to prescribe the activities of nationals, even when they are outside the sovereign of

²³¹ Siddiqi, above.

²³² Siddiqi, above.

²³³ Siddiqi, above.

²³⁴ Siddiqi, above.

²³⁵ Stephan Wilkes and Teresa Schiller "International Jurisdiction in Cyberspace: Which State may Regulate the Internet?" (1997) Federal Communications Law Journal [on-line]. <http://web2.westlaw.com/Welcom/WestlawInternational/default.wl?RS=WLW2.72&VR=2.0&FN=top&MT=WestlawInternational&SV=Split> (last accessed 14 February 2002).

²³⁶ Wilkes and Schiller, above.

²³⁷ Wilkes and Schiller, above.

nationality.”²³⁸ Again, this principle only applies to its own nationals, but does not give a country jurisdiction to sue foreign online pharmacies operated by foreign nationals.

However, a country can also claim jurisdiction under international law principles in cases where the state seeks “to protect its interest by criminalising an act that a sovereign considers to be threat to its national security.”²³⁹ At first sight, this principle would give countries jurisdiction concerning foreign online businesses. However, it is most likely that some countries would take advantage of it and expand their jurisdictional power which might lead to disputes with other states.²⁴⁰ The key issue is when is an activity on the Internet an act of crime? Though it might be easily answered for pornographic web sites, it will be more difficult for Internet pharmacies.

Finally, jurisdiction can be claimed under the principle of universal jurisdiction which enables all countries “to define and prescribe punishment in a limited set of circumstances, including piracy, slavery, hijacking, genocide, war crimes and the unlawful interference with aircraft.”²⁴¹ This principle “does not require a direct connection such as the place of the offense, the nationality of the offender, or the effects of the offense on the prescribing state.”²⁴² However, this jurisdiction only applies to the most serious crimes “which incur international criminal liability.”²⁴³ It can hardly be argued that the fraudulent and illegal sale of medicine over the Internet falls within the scope of the principle.

²³⁸ Asaad Siddiqi “Welcome to the City of Bytes? An Assessment of the Traditional Methods Employed in the International Application of Jurisdiction over Internet Activities- Including A Critique of Suggested Approaches” (2001) New York International Law Review [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²³⁹ Siddiqi, above. See also Wilkes and Schiller, above.

²⁴⁰ Siddiqi, above.

²⁴¹ Siddiqi, above.

²⁴² Stephan Wilkes and Teresa Schiller “International Jurisdiction in Cyberspace: Which State may Regulate the Internet?” (1997) Federal Communications Law Journal [on-line]. http://web2.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLW2.72&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 14 February 2002).

²⁴³ Siddiqi, above.

However, courts may be authorised to hear the case under international law if one of its own nationals is one of the litigants. While the so-called adjudicate jurisdiction is widely accepted in criminal cases, only "a few sovereigns have developed a complex set of laws whereby jurisdiction may be exercised against defendants who are not ordinarily within court's general jurisdiction by virtue of the defendants' residence or domicile."²⁴⁴ Although this jurisdiction may apply to foreign online pharmacies, it is not acknowledged on the broad international level. Even if a court would decide a foreign based case under the adjudicated jurisdiction, there would be still difficulties to enforce the judgment in another state's territory. On an international level, the other sovereign might "consider such enforcement to be violative of their sovereignty"²⁴⁵ especially as the adjudicative jurisdiction is not established for Internet businesses. As result, even under the principle of adjudicate jurisdiction, the current international law does not apply to online pharmacies. Thus, under traditional bases of international law, a country cannot file a lawsuit against a foreign online pharmacy due to the lack of jurisdiction. Every action in a domestic court against a foreign national, whether it is the web site operator, the provider or the pharmacist who sells the products, would be void and could lead to compensation. Moreover, the country may lose its reputation on an international level if it sues companies without having jurisdiction to do so. The growing Internet business, however, will lead to significant changes as many countries call for actions on an international level to ensure that "health care web sites owners and operators [do not] escape the imposition of existing laws."²⁴⁶

²⁴⁴ Siddiqi, above. See generally Frederic L. Kirgis Jr., "Alien Tort Claims, Sovereign Immunity and International Law in U.S. Courts" (1988) *American Journal of International Law* [on-line].

<<http://web2.westlaw.com/Welcoming/WestlawInternational/default.wl?RS=WLW2.72&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002).

²⁴⁵ Siddiqi, above.

²⁴⁶ Nicole A. Rothstein "Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada" (2001) *Federal Communications Law Journal* [on-line].

<<http://international.westlaw.com/Welcoming/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002).

2 The United States' Attempt To Set Up Internet Jurisdiction

Due to the growing use of Internet pharmacies and the amount of litigation, United States' courts struggle with Internet jurisdiction problems. While a foreign-based online pharmacy violates United States' law by selling prescription or unapproved drugs to consumers in the United States,²⁴⁷ the jurisdiction over foreign companies is, as reviewed above, limited. The challenge courts face is to find a kind of loophole in the current law to file lawsuits against foreign online pharmacies in domestic court. In cases where "the defendant enters into contracts with residents of a foreign jurisdiction that involve the knowing and repeated transmission of computer files over the Internet, personal jurisdiction is proper."²⁴⁸ Under personal jurisdiction, "a plaintiff may chose to sue a defendant upon a particular claim"²⁴⁹ in a geographically limited place. In *State by Humphrey v Granite Gate Resort, Inc.* the court considered, for the first time, the jurisdiction over a web site in an international context and held "that personal jurisdiction over the defendant was justified because the web site was accessible by Minnesota residents, and the defendant had directed its advertisements at customers in the United States, including residents of Minnesota."²⁵⁰ In recent years, several courts ruled that foreign defendants, due to their Internet activities, can be sued in a United States' court under

²⁴⁷ Melissa K. Cantrell "The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites" (2001) West Virginia Law Review [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁴⁸ Asaad Siddiqi "Welcome to the City of Bytes? An Assessment of the Traditional Methods Employed in the International Application of Jurisdiction over Internet Activities- Including A Critique of Suggested Approaches" (2001) New York International Law Review [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁴⁹ Richard S. Zembeck "Jurisdiction and the Internet: Fundamental Fairness in the Networked World of Cyberspace" (1996) Albany Law Journal of Science and Technology [on-line].

<http://web2.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLV2.72&VR=2.0&SV=Split&FN=_top&MT=WestlawInternational> (last access 14 February 2002).

²⁵⁰ Cantrell, above. See also Minnesota Court of Appeal *State by Humphrey v Granite Gate Resort, Inc.*, Judgment (5 September 1997) [on-line].

<http://web2.westlaw.com/Find/Default.wl?SerialNum=1997185803&FindType=Y&USID=%2E%2C744d5e24d52f413deb2a9b807930a36a&AP=&RS=WLV2.72&VR=2.0&SP=&SV=Split&MT=WestlawInternational&FN=_top&RLT=CLID_FQRLT024313> (last accessed 14 February 2002). Although the following cases were civil litigation, it is worth to survey them due to the possible approach for international jurisdiction.

personal jurisdiction. In *Quokka Sports, Inc. v Cup International, Ltd.* a California court held "that in this case the defendant set up web sites that specifically targeted the United States."²⁵¹ However, in these cases an activity more than just a web site was needed to establish personal jurisdiction over a foreign defendant. Thus, a lawsuit against a foreign based online pharmacy for the sale of medicine over the Internet to United States consumers can only be filed if there is proof that the defendant does business over the Internet. Although every contract between the consumer and the online pharmacy would be enough to establish such business, United States' authorities might struggle to prove the existence of a contract. It is most unlikely that consumers work together with authorities due to the risk of being prosecuted for importing prescription or unapproved drugs into the United States. According to United States' law, "it is illegal for anyone to ship prescription drugs that are not approved by FDA into the [the United States] even though the drug may be legal to sell in that pharmacy's country,"²⁵² but consumers are deterred from admitting their offence. Even if authorities were able to prove a contact, it is still unclear whether personal jurisdiction could be applied in criminal cases. It is most unlikely because the lawsuit would intervene with another sovereigns obligation.

Different concerns raise "passive web sites that do little more than make information available to these who are interested in."²⁵³ United States' courts held that no "personal jurisdiction over a foreign defendant based solely on maintenance of a passive web site"²⁵⁴ could be exercised. The Ninth Circuit stated in *Cybersell, Inc. v Cybersell, Inc.* that "the mere presence of a passive web site on the Internet does not constitute the

²⁵¹ Cantrell, above.

²⁵² David Mills "Cybermedicine: The Benefits and Risks of Purchasing Drugs over the Internet" (2000) *Journal of Technology Law & Policy* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁵³ Asaad Siddiqi "Welcome to the City of Bytes? An Assessment of the Traditional Methods Employed in the International Application of Jurisdiction over Internet Activities- Including A Critique of Suggested Approaches" (2001) *New York International Law Review* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

minimum contacts needed to subject a person to the jurisdiction of every court and that something more 'either interactivity or purposeful direction', is needed to justify jurisdiction."²⁵⁵ Concerning the sale of medicine over the Internet it will be more likely that the web site is interactive and has a commercial nature. Then, courts might be able to find a contact between the user and the site owner or the person who sells the pharmaceuticals.²⁵⁶ Could the jurisdiction be extended to criminal cases? The approach of the United States' courts to establish jurisdiction over foreign based web sites might enable lawsuits of overseas online pharmacies in United States courts. However, the increasing number of online pharmacies will make it more difficult to "monitor all web sites at all time"²⁵⁷ and to establish a jurisdiction for all foreign based web sites regardless of the commercial activities aimed at United States consumers.

IV Online Pharmacies On An International Level – Possible Approaches

The current jurisdiction limits possibilities to bring actions at a domestic level against foreign web sites. Many nations are co-operating with each other "in an attempt to address the problem but a formalised international approach does not yet exist."²⁵⁸ While a state's border cannot be made secure from anything a national might buy from a foreign web site, the more important seems to be international co-operation. To make the world wide

²⁵⁴ Cantrell, above.

²⁵⁵ Siddiqi, above. See Ninth Circuit, Arizona Court of Appeal *Cybersell, Inc. v Cybersell, Inc.*, Judgment (2 December 1997) [on-line].
<http://web2.westlaw.com/Find/Default.wl?SerialNum=1997235568&FindType=Y&USID=%2E%2C744d5e24d52f413deb2a9b807930a36a&AP=&RS=WLV2.72&VR=2.0&SP=&SV=Split&MT=WestlawInternational&FN=_top&RLT=CLID_FQRLT2521313> (last accessed 7 February 2002).

²⁵⁶ Siddiqi, above.

²⁵⁷ David B. Brushwood "Responsive Regulation of Internet Pharmacy Practice" (2001) *Annals of Health Law* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLV2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁵⁸ Sean P. Haney "Pharmaceutical Dispensing in the "Wild West": Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies" (2000) *William and Mary Law Review* [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLV2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

business safe requires either an effective regulation of online pharmacies or a new base of jurisdiction on the international plane. This part focuses on possible regulatory issues and the probability of international jurisdiction over Internet pharmacies. It therefore addresses questions such as: should there be a treaty-based system of international jurisdictional rules or would a sui generis regulation of the Internet pharmacy business be more effective and appropriate?

A Regulatory Issues

The Regulation of the Internet pharmacy market would be the most effective way of ensuring the protection of the customer's health. In setting up guidelines to clarify issues such as a licence system of online pharmacies, sale practices or the liability of Internet service providers, web site operators and anyone who sells medication over the Internet would make it easier for the industry to comply with the state's demand for a safe consumer service over the Internet and it would also be easier for authorities to deal with the unlawful actions of online pharmacies. However, internet regulations raise many crucial questions. How should the online pharmacy business be regulated and who should have the authority to do so? While the jurisdictional authority is clear on a domestic level,²⁵⁹ it is still a regulatory challenge on an international level. There is no body which has the authority to set up guidelines. Moreover, there will be a controversial debate about which law should apply or what specific role nations should play in the regulation challenge of online pharmacies. Currently, only a few nations are interested in setting up effective regulations to "ensure an adequate level of confidentiality and control over consumers' personal health information; reliability of online information; and direct redress for

²⁵⁹ It should be mentioned that in the United States due to the federal and state jurisdictional authority, several agencies have claimed that the problem with online pharmacies does not fall within their authority. See Kerry Toth Rost "Policing the "Wild West" World of Internet Pharmacies" (2000) Food and Drug Law Journal [on-line].
<<http://international.westlaw.com/Welcom/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002). However, in other countries like Germany the regulatory competency are clear.

invasion of privacy and unfair, deceptive and fraudulent trade practices."²⁶⁰ However, the Internet applies to users all over the world. Thus, every nation needs to be involved in the debate otherwise, they might feel that their interests were not fully addressed by the lawmakers. Online pharmacies "are not confined to one particular jurisdiction"²⁶¹ or the interest of a few countries. It is most unlikely that a country itself may be able to regulate the business without the co-operation between other countries. It will be essential to set up working groups to discuss approaches countries have taken to regulate online pharmacies and consider other issues relating to the sale of drugs over the Internet.²⁶² Recently, the WHO in co-operation with other nations has addressed the problem. Although an international regulation does not exist, "the WHO has stressed co-operation among member nations to enforce particular national standards and prohibit illegal international sales."²⁶³ Recently, U.S. agencies have acknowledged that only co-operation with foreign governments will enable authorities on domestic level to bring action against the unlawful practice of online pharmacies.²⁶⁴ However, it will be a long time before the first international guidelines will be introduced and enforced.

At present, several Internet pharmacies try to distant themselves from fraudulent and illegal online pharmacy practices by setting up self-

²⁶⁰ Nicole A. Rothstein "Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada" (2001) Federal Communications Law Journal [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁶¹ Amy J. Oliver "Internet Pharmacies: Regulation of a Growing Industry" (2000) Journal of Law, Medicine & Ethics [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁶² Toth Rost, above.

²⁶³ Sean P. Haney "Pharmaceutical Dispensing in the "Wild West": Advancing Health Care and Protecting Consumers Through the Regulation of Online Pharmacies" (2000) William and Mary Law Review [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁶⁴ William K. Hubbard *Statement before the Subcommittee on Oversight and Investigations Committee on Commerce U.S. House of Representatives* (25 May 2000) [on-line]. <<http://www.fda.gov/ola/2000/internetsale.html>> (last accessed 10 February 2002). Hubbard stated that "the FDA's Office of Criminal Investigation maintains ongoing liaison with numerous government agencies in Canada, the U.K., Spain, Germany, Belgium, the Netherlands, Ireland, Brazil, Singapore and other."

regulations. Although this new initiative “reflects an awareness of the effects of pharmaceutical marketing and a desire to responsibly promote drugs in order to minimise misuse and injury,”²⁶⁵ critics argue that “this complex issue should [not] be addressed solely by the private sector.”²⁶⁶ Furthermore, “self-regulation has proved to have limited efficacy”²⁶⁷ and “is less effective than a comprehensive statutory framework.”²⁶⁸ Although self-regulation is a unique approach by the industry to policy itself,²⁶⁹ the “enforcement of these principles and codes remain unsettled.”²⁷⁰ Due to the fact that “self-regulation is largely industry specific [and] powerless to close the loopholes”²⁷¹ of the current lack of regulation on domestic or international level, there is no need for the pharmacy industry to follow such policy. Nevertheless, the willingness of online pharmacies “to bind themselves to a set of privacy principles”²⁷² should be acknowledged. The approach might be helpful when it comes to an enactment of new legislation addressing online pharmacies on international level.

²⁶⁵ Sara E. Zeman “Regulation of Online Pharmacies: A Case for Cooperative Federalism” (2001) *Annals of Health Law* [on-line].
 <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁶⁶ David Mills “Cybermedicine: The Benefits and Risks of Purchasing Drugs over the Internet” (2000) *Journal of Technology Law & Policy* [on-line].
 <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁶⁷ Janlori Goldman and Zoe Hudson “Virtually Exposed: Privacy and E-Health; Privacy Concerns are Keeping Consumers From Reaping the Full Benefit of Online Health Information” (2000) The People-to-People Health Foundation, Inc. [on-line] http://www.lexis.com/research/retrieve/frames?_m=fad3ad7d53ac7b31095879582a09c4e1&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLSZV-1S1WS&_md5=706f28c59a44c186e582e91b2b906c74> (last accessed 7 February 2002).

²⁶⁸ Eric M. Peterson “Doctoring Prescriptions: Federal Barriers to combating Prescription Drug Fraud Against Online Pharmacies in Washington” (2000) *Washington Law Review* [on-line].
 <http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁶⁹ Goldman and Hudson, above.

²⁷⁰ Bruce Merlin Fried, Gadi Weinreich, Gina M. Cavalier and Kathleen J. Lester “E-Health: Technologic Revolution Meets Regulatory Constraint; An Internet-Driven Health System Poses New Challenges for an Area Already Thick With Regulations” (2000) The People-to-People Health Foundation, Inc. [on-line].
 <http://www.lexis.com/research/retrieve/frames?_m=fad3ad7d53ac7b31095879582a09c4e1&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLSZV-1S1WS&_md5=706f28c59a44c186e582e91b2b906c74> (last accessed 7 February 2002).

²⁷¹ Peterson, above.

B A New Base Of International Jurisdiction

Despite moves to regulate online pharmacies on an international level, it seems necessary to consider a new base of international jurisdiction, as the current international jurisdiction limits governments' and agencies' possibilities for prosecuting a foreign based web site in domestic courts. Many countries, especially the United States, already call for a new base jurisdiction due to the threat to their nationals' health of fraudulent or dangerous Internet practices. Authorities are aware that the Internet is more or less, at present, a shield for illegal activities. There is no "potential risk for criminal prosecution or civil liability"²⁷³ for a foreign based online pharmacy. While the United States in several Internet connected cases argued that jurisdiction to sue an overseas company is established as long as there is a minimum contact between the defendant and the Internet user, the attempt can surely be questioned as it extends the United States jurisdiction contrary to the traditional bases of jurisdiction. This approach could "damage U.S. relations with its treaty-making partners."²⁷⁴ It is widely assumed that a state may not extend its jurisdiction contrary international law. The mere fact that personal jurisdiction would authorise US courts to judge over foreign-based web sites "is insufficient to justify the state to exercise jurisdiction in another state's territory."²⁷⁵ Due to these facts, it seems necessary to introduce a new base of international jurisdiction to end unapproved attempts and to guarantee world wide accepted rules. Before a new international jurisdictional rule may be introduced, it must be clear where the action or offence has taken place. Should it be the place where

²⁷² Goldman and Hudson, above.

²⁷³ Melissa K. Cantrell "The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Websites" (2001) West Virginia Law Review [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁷⁴ Andrew L. Strauss "Where America Ends and the International Order Begins: Interpreting the Jurisdictional Reach of the U.S. Constitution in Light of a Proposed Hague Convention on Jurisdiction and Satisfaction of Judgments" (1998) Albany Law Review [on-line].
<http://web2.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLW2.72&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 14 February 2002).

²⁷⁵ Stephan Wilkes and Teresa Schiller "International Jurisdiction in Cyberspace: Which State may Regulate the Internet?" (1997) Federal Communications Law Journal [on-line].

the server is located or even the place of downloading? Once courts have identified the location of the offence, the discussion about the jurisdiction may be less complicated. In a number of cases jurisdiction may already be given because the unlawful action was committed within the country's territory. In Internet Gambling cases, United States courts held that "the location of the action or offense [is] the place of downloading."²⁷⁶ If one would argue with the place of downloading, the jurisdictional problem might be solved. However, it is more likely that courts will identify the place of action in the server located overseas. Then, "the law at issue can only be applied extraterritorially."²⁷⁷ Some commentators argue for a treaty-based system of international jurisdictional rules.²⁷⁸ Such treaty would undoubtedly have many advantages. Firstly, it would have to be an explicit regulation every nation must comply with. Secondly, the dispute about the jurisdiction of domestic courts over foreign pharmacy web sites would be settled and authorities would not have to face difficulties to sue unlawful practices of online pharmacies. Furthermore, it is argued that "such a treaty could correct the discriminatory way in which American citizens²⁷⁹ are subjected to overly-broad assertions of jurisdiction by European countries."²⁸⁰ Member states of the EU have already set up regulations for "a European jurisdiction and satisfaction of judgments treaty regime under which principles of jurisdiction are well-defined."²⁸¹ Indeed, the European jurisdictional system is unique. It makes it possible to sue an online pharmacy operating from a Member state.²⁸² The European provisions guarantee adequate co-ordination of jurisdictional responsibilities

http://web2.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLW2.72&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split (last accessed 14 February 2002).

²⁷⁶ Cantrell, above.

²⁷⁷ Cantrell, above.

²⁷⁸ Strauss, above.

²⁷⁹ It should be mentioned that it also applies to other citizens except those living in a country belonging to the European Union.

²⁸⁰ Andrew L. Strauss "Where America Ends and the International Order Begins: Interpreting the Jurisdictional Reach of the U.S. Constitution in Light of a Proposed Hague Convention on Jurisdiction and Satisfaction of Judgments" (1998) Albany Law Review [on-line].

<http://web2.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLW2.72&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 14 February 2002).

²⁸¹ Strauss, above.

²⁸² See lawsuits concerning the Dutch online pharmacy DocMorris in German courts.

and could be an appropriate start for treaty-based international jurisdictional rules.

Several commentators "have argued enacting *sui generis* rules for the problems created by the Internet rather than waiting for caselaw and statutes to catch up by incrementally analogizing the Internet to the old principles."²⁸³ *Sui generis* regulations can include "statutes that directly regulate [actions of Internet pharmacies]; rules and arguments among Internet Service Providers [or rules] in the form of norms that arise from interaction in cyberspace."²⁸⁴ The success of these *sui generis* rules in controlling the sale of medicine over the Internet can be questioned. Such regulations might not be supported but more important "the statutes are either under-enforced or subject to substantial exceptions."²⁸⁵

Others argue that "cyberspace should either be unregulated or left down."²⁸⁶ However, that would be dangerous as the Internet without adequate regulation would lead to a place where unlawful activities can be committed without the fear of judicial consequences. It seems, regardless what side one would agree with, that a new base of international jurisdiction would "require existing sovereignties to relent and give up whatever control they can muster on more traditional bases."²⁸⁷ However, to uphold traditional bases will be impossible as the new technology forces lawmakers to face the inability of the current law and to evolve new standards. Whatever a new base of international jurisdiction might be, it only can be achieved in co-operation of all nations.

²⁸³ Asaad Siddiqi "Welcome to the City of Bytes? An Assessment of the Traditional Methods Employed in the International Application of Jurisdiction over Internet Activities-Including A Critique of Suggested Approaches" (2001) *New York International Law Review* [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002). See also Shubha Ghosh "Grey Market in Cyberspace" (1999) *Journal of Intellectual Property Law* [on-line]

<http://web2.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLW2.72&VR=2.0&SV=Split&FN=_top&MT=WestlawInternational> (last accessed 7 February 2002).

²⁸⁴ Ghosh, above.

²⁸⁵ Ghosh, above.

²⁸⁶ Siddiqi, above.

V Conclusion

People access the Internet for "an easy, fast and potentially robust source"²⁸⁸ of information. The use of the Internet will rapidly increase within the next years as more and more companies respond to the widespread consumer use and expand their business using the new medium. Today, "almost anything can be bought over the Internet and delivered right to your front door"²⁸⁹ and it is no surprise that even pharmacies went online revolutionising the health care industry. Online pharmacies offer convenience, low prices and efficiency not only to the elderly and people who live in rural areas but everyone living in today's busy world. There certainly are many benefits. Take a few minutes of your lunch break or between your appointments and you can order whatever pharmaceuticals you want from wherever in the world. Technology is great. However, the enormous benefit is overshadowed by substantial risks. Buying medicine from certain web sites "may do more harm than good."²⁹⁰ As in every business, online pharmacies are not secure from fraudulent and illegal practices. In fact, many companies operating Internet pharmacies are not complying with the law selling prescription medicine without a valid prescription or unapproved and illegal drugs. Thus, the consumer's health is at great risk. Due to the increasing number of pharmacy web sites, many concerns have been raised and it seems that there are more questions than answers.

There are several attempts of the United States, New Zealand and Europe at regulating the Internet which do not differ greatly. While the United States and New Zealand have begun to review their laws due to the

²⁸⁷ Siddiqi, above.

²⁸⁸ Nicole A. Rothstein "Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada" (2001) Federal Communications Law Journal [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁸⁹ David Mills "Cybermedicine: The Benefits and Risks of Purchasing Drugs over the Internet" (2000) Journal of Technology Law & Policy [on-line].
<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

²⁹⁰ Mills, above.

increasing number of legal actions against online pharmacies operating from their territory, Europe has introduced the Directive on electronic commerce addressing issues relating to the Internet. However, these approaches "will likely prove inadequate to control illegal practices due to the global nature of the Internet."²⁹¹ The United States still does not have adequate Internet pharmacy regulations. Although the states have already begun to regulate online pharmacies, these regulations are ineffective. Due to the government system, pharmacy provisions "must comply with both national and state laws."²⁹² Thus, "co-operation between the states and federal government will be required to effectively regulate the industry and protect consumers."²⁹³

The outcome of the New Zealand lawsuit was more significant as parliament passed a new legislation prohibiting the import and export of prescription medicine. Nevertheless, there are still loopholes in the existing law when it comes to the sale of pharmacy only medicine and restricted medicine. Currently, New Zealand law seems to be adequate to deal with the sale of medicine from overseas, partly because of its geographical isolation, but it is most likely that online pharmacies will bring new challenges for the legislation in the coming years.

The attempt on the European level seems less effective due to the different laws of the Member states. Furthermore, the Directive on electronic commerce does not explicitly apply to the sale of pharmaceuticals over the Internet. Nevertheless, Member states must comply with other EU provisions which inter alia prohibit any discrimination or restriction to access their market. Even without explicit regulations, Internet pharmacies

²⁹¹ Amy J. Oliver "Internet Pharmacies: Regulation of a Growing Industry" (2000) *Journal of Law, Medicine & Ethics* [on-line].

<<http://international.westlaw.com/Welcoming/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002).

²⁹² Nicole A. Rothstein "Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada" (2001) *Federal Communications Law Journal* [on-line].

<<http://international.westlaw.com/Welcoming/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002).

²⁹³ Oliver, above.

seem to be legal as long as they are controlled and legalised by the Member state. However, all countries have failed to deal with the crucial issue of regulation to control the online sale of medicine on the international level. It is obvious that "the law has lagged behind the recent developments in the delivery of health care."²⁹⁴ International law provisions do not apply to online pharmacies and authorities struggle to deal with the subject matter. The impossibility of monitoring fraudulent or illegal web sites or to prosecute a foreign Internet pharmacy in domestic courts due to the limited international jurisdiction are just a few difficulties authorities face. Despite the United States' attempt to prosecute foreign online businesses under the principle of personal jurisdiction, which certainly can be questioned, there are no other approaches relating to the subject matter. Countries already call for explicit regulations and a new base of international jurisdiction. No solution, however, has been formalised. Indeed, it is hard to set up effective regulation because of the unknown future of online pharmacies and the different ideas and interests countries follow. Nations must continue to work together nevertheless as "the law must continue to grow and attempt to accommodate new technology so that society can function in a prosperous, yet safe manner."²⁹⁵ It is essential that "regulations should only eliminate unlawful Internet pharmacies [and] enable the growth of a valuable addition to both the healthcare industry and e-commerce."²⁹⁶ The goal should be "to promote the health and safety of the Internet users."²⁹⁷ That can be achieved best through approaches which "[allow] the law to adopt with time

²⁹⁴ Kelly K. Gelein "Are Online Consultations a Prescription For Trouble? The Uncharted Waters Of Cybermedicine" (2000) Brooklyn Law Review [on-line].
<<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002).

²⁹⁵ Joanna M. Carlini "Liability on the Internet: Prescription Drugs and the Virtual Pharmacy" (2000) Whittier Law Review [on-line].
<http://www.lexis.com/research/retrieve/frames?_m=e7fb4d96ad7819a2c00a60c3bfff9b95&_fmtstr=CITE&docnum=1&_startdoc=1&_startchk=&wchp=dGLStk-|SIWk&_md5=ecfec75d774e1db179a272899a801205> (last accessed 7 February 2002).

²⁹⁶ Kerry Toth Rost "Policing the "Wild West" World of Internet Pharmacies" (2000) Food and Drug Law Journal [on-line].
<<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=top&MT=WestlawInternational&SV=Split>> (last accessed 7 February 2002).

²⁹⁷ Carlini, above.

instead of sweeping revisions that will lead to a cycle of endless transformations after each 'revolution' like the Internet."²⁹⁸

Constitution For The United States of America

Commerce Clause

Article I

Section 8

The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States;

To borrow Money on the credit of the United States,

To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes;

²⁹⁸ Asaad Siddiqi "Welcome to the City of Bytes? An Assessment of the Traditional Methods Employed in the International Application of Jurisdiction over Internet Activities- Including A Critique of Suggested Approaches" (2001) New York International Law Review [on-line].

<http://international.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLIN2.71&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split> (last accessed 7 February 2002).

Appendix 1

Constitution For The United States of America

Commerce Clause¹

Article I.

Section. 8.

The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States;

To borrow Money on the credit of the United States;

To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes;

...

¹ The Commerce Clause is adopted of the Constitution of the United States of America [online]. <http://www.constitution.org/constit_.htm> (last accessed 10 February 2002).

Appendix 2

Directive 2000/31/EC of the European Parliament and of the Council (Directive on electronic commerce)¹

Consideration Reason:

- (21) The scope of the co-ordinated field is without prejudice to future Community harmonisation relating to information society services and to future legislation adopted at national level in accordance with Community law; the co-ordinated field covers only requirements relating to on-line activities such as on-line information, on-line advertising, on-line shopping, on-line contracting and does not concern Member States' legal requirements relating to goods such as safety standards, labelling obligations, or liability for goods, or Member States' requirements relating to the delivery or the transport of goods, including the distribution of medicinal products; the co-ordinated field does not cover the exercise of rights of pre-emption by public authorities concerning certain goods such as works of art.

¹ The text of the Directive on electronic commerce is adopted from http://web2.westlaw.com/Welcome/WestlawInternational/default.wl?RS=WLW2.72&VR=2.0&FN=_top&MT=WestlawInternational&SV=Split (last accessed 10 February 2002).

Article 2

Definitions

For the purpose of this Directive, the following terms shall bear the following meanings:

- (h) 'co-ordinated field': requirements laid down in Member States' legal systems applicable to information society service providers or information society services, regardless of whether they are of a general nature or specifically designed for them.

Article 3

Internal market

1. Each Member State shall ensure that the information society services provided by a service provider established on its territory comply with the national provisions applicable in the Member State in question which fall within the co-ordinated field.
2. Member States may not, for reasons falling within the co-ordinated field, restrict the freedom to provide information society services from another Member State.
3. Paragraphs 1 and 2 shall not apply to the fields referred to in the Annex.
4. Member States may take measures to derogate from paragraph 2 in respect of a given information society service if the following conditions are fulfilled:
 - (a) the measures shall be:

- (i) necessary for one of the following reasons:
 - public policy, in particular the prevention, investigation, detection and prosecution of criminal offences, including the protection of minors and the fight against any incitement to hatred on grounds of race, sex, religion or nationality, and violations of human dignity concerning individual persons,
 - the protection of public health,
 - public security, including the safeguarding of national security and defence,
 - the protection of consumers, including investors;
 - (ii) taken against a given information society service which prejudices the objectives referred to in point (i) or which presents a serious and grave risk of prejudice to those objectives;
 - (ii) proportionate to those objectives;
- (b) before taking the measures in question and without prejudice to court proceedings, including preliminary proceedings and acts carried out in the framework of a criminal investigation, the Member State has:
- asked the Member State referred to in paragraph I to take measures and the latter did not take such measures, or they were inadequate,
 - notified the Commission and the Member State referred to in paragraph 1 of its intention to take such measures.

5. Member States may, in the case of urgency, derogate from the conditions stipulated in paragraph 4(b). Where this is the case, the measures shall be notified in the shortest possible time to the Commission and to the Member State referred to in paragraph 1,

indicating the reasons for which the Member State considers that there is urgency.

6. Without prejudice to the Member State's possibility of proceeding with the measures in question, the Commission shall examine the compatibility of the notified measures with Community law in the shortest possible time; where it comes to the conclusion that the measure is incompatible with Community law, the Commission shall ask the Member State in question to refrain from taking any proposed measures or urgently to put an end to the measures in question.

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