

## Internet Pharmacies: Global threat requires a global approach to regulation

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### Abstract

This paper investigates the growing phenomenon of selling drugs and medical services over the Internet via Internet Pharmacies. It discusses some of the benefits of Internet Pharmacies and some serious concerns that they bring for regulators, governments and global consumers. In addition, the paper compares regulatory frameworks governing the operation of Internet Pharmacies in the United Kingdom (UK) and the United States (US), to illustrate some of the challenges related to differences. Some of these comparisons relate to regulatory structure, advertising of prescription drugs, online prescribing, data protection, policy on importing drugs for personal use and self-regulation/certification of websites. In assessing reasons for differences in the two jurisdictions, the paper concludes that these are due to various historic, economic, geographic and political factors. The paper argues that continuing regulatory challenges arise due to the nature of the Internet, jurisdiction issues, economic realities, and a lack of harmonisation of regulatory policy at an international/global level. The paper further argues that a global approach is needed to regulate online medical services, because of the potential threat to the health and well-being of the global community.

### 1. Introduction

The widespread use of the Internet for commercial activities (electronic commerce) has resulted in the global access to drugs and medical services at the click of a button. The borderless nature of the Internet, however, creates difficulty in regulating electronic commerce within a physical jurisdiction, especially when websites originate outside that jurisdiction. In the absence of appropriate harmonised laws, treaties and cooperative agreements between nation states, online sellers can evade regulation in certain jurisdictions by engaging in regulatory arbitrage (i.e. operating websites in a jurisdiction which has the least restrictive regulatory framework). In many instances those evading regulation do so in order to engage in illegal activities. There is need for a concerted global approach to address such (illegal) activities relating to electronic commerce, especially where health and medical issues are concerned. The seriousness of this issue is encapsulated in a 2005 speech to the 108<sup>th</sup> Congress given by US Senator Dianne Feinstein:

“Rogue internet pharmacies continue to pose a serious threat to the health and safety of Americans...Simply put, a few unethical physicians and pharmacists have become drug suppliers to a nation. They provide pharmaceuticals – including powerful narcotics and anti-depressants – to patients without an in-person examination, based solely on an online questionnaire. The longer we wait to take action, the more people will be killed or seriously injured as a result of this unethical behavior.”<sup>1</sup>

Unfortunately, the problem of ‘rogue’ pharmacies (and the illegal online selling of drugs) is not confined to a ‘few unethical physicians and pharmacists’, but exists on a wider scale. Examples

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<sup>1</sup> <http://www.senate.gov/~feinstein/05releases/r-internet-pharm.htm>

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include: In the UK, the National Audit Office (2003) reported that one percent (1%) of the public surveyed had bought prescription medicines on the Internet (without a prescription) for various conditions such as obesity, prostate cancer, hair loss, or erectile dysfunction<sup>2</sup>; In 2004, according to Pfizer (the world's largest pharmaceutical company and makers of the drug Viagra) approximately 350,000 websites sold fake Viagra or directed users to a site that sold fake Viagra<sup>3</sup>; In 2005 the US Drug Enforcement Administration (DEA) launched operation Cyber X which led to the shutdown of more than 4600 rogue pharmacies<sup>4</sup>.

This paper focuses on the selling of drugs and medical services via Internet Pharmacies. It first gives a brief introduction to Internet Pharmacies, then discusses some benefits and concerns regarding the operation of Internet Pharmacies. It then gives a comparison of some aspects of the regulatory frameworks of two major jurisdictions, with a view to discussing the challenges that some differences bring. The paper attempts to give reasons for some of the differences seen, and argues that a global approach is needed to regulate Internet Pharmacies (especially those engaged in illegal activities), because of the potential threat to the health of the global community.

## 2. Internet Pharmacies

Various drugs and medical services can be accessed online, via businesses known as 'Internet Pharmacies'<sup>5</sup>, also called 'cyberpharmacies', 'ePharmacies', and 'online pharmacies' among other names. An Internet Pharmacy is used to sell a variety of products including beauty products, over-the-counter drugs (which does not require a prescription) and prescription drugs (which requires a prescription issued by a licensed health professional)<sup>6</sup>. Some Internet Pharmacies also provide a variety of online services (e.g. advice on medications). In the US Internet Pharmacies have been in existence since January 1999 (with the opening of Soma.com)<sup>7</sup>, following a long history (from 1872) of selling drugs via mail-order<sup>8</sup>. In the UK Internet Pharmacies began operations a few months later (November 1999) with the opening of Pharmacy2u.co.uk<sup>9</sup>.

While many Internet pharmacies operate within the law, some 'rogue' pharmacies, are involved in various illegal acts such as selling prescription drugs without a valid prescription,

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<sup>2</sup> The NAO study surveyed 2000 members of the public aged 15 years or over.

See: NAO Report. *Safety, quality, efficacy: regulating medicines in the UK*, 16<sup>th</sup> January 2003  
[http://www.nao.org.uk/publications/nao\\_reports/02-03/0203255.pdf](http://www.nao.org.uk/publications/nao_reports/02-03/0203255.pdf)

<sup>3</sup> Libbenga, J, Rogue Pharmacies still thriving, *The Register*, 21<sup>st</sup> December 2004  
[http://www.theregister.co.uk/2004/12/21/rogue\\_pharmacies\\_still\\_thriving/](http://www.theregister.co.uk/2004/12/21/rogue_pharmacies_still_thriving/)

<sup>4</sup> DEA News Release, 19<sup>th</sup> December 2005: <http://www.usdoj.gov/dea/pubs/pressrel/pr121905.html>

<sup>5</sup> S. Crawford, Internet Pharmacy: Issues of Access, Quality, Costs and Regulation. *Journal of Medical Systems*, Vol.27, No.1, Feb 2003

<sup>6</sup> Note that drugs in the UK are placed into three categories under the Medicines Act 1968 (as amended) namely: (i) Prescription-only (Section 58) – which can only be sold with a valid prescription; (ii) Pharmacy only (Section 60) – which can must be sold in consultation with a pharmacist; and (iii) General Sales List (Section 5) – which do not require any prescription or consultation before sale. In the US only two categories exist namely: prescription drugs and over-the-counter drugs (not requiring a prescription). In this paper drugs requiring a prescription are simply called prescription drugs.

<sup>7</sup> S. Crawford, Internet Pharmacy: Issues of Access, Quality, Costs and Regulation. *Journal of Medical Systems*, Vol.27, No.1, Feb 2003.

<sup>8</sup> As early as 1872, Americans began purchasing goods via mail order, after the world's first general merchandise mail-order company was started in the US by Aaron Montgomery Ward  
<http://www.graveyards.com/rosehill/ward.html>

<sup>9</sup> Britain's first Internet pharmacy opens. *The Pharmaceutical Journal*, Vol 263, No 7073, p849, Nov, 27, 1999.

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selling fake or poor quality drugs, and providing online medical consultations for prescribing and dispensing drugs. These 'rogue' Internet Pharmacies present a great danger to the public due to the potential harm which can be caused by their illegal activities.

## 2.1 Some benefits and concerns

There are many benefits as well as concerns related to the operation and use of Internet Pharmacies<sup>10</sup>.

Benefits include:

- *Ease, convenience & increased choice.* Online services allow 24-7 access, and easy comparison of products. This is especially relevant to consumers who live in sparsely populated areas where there are no pharmaceutical services, and disabled people who have difficulty in travelling to a Pharmacy<sup>11</sup>, among others;
- *Increased consumer information and information exchange.* Through online searches, consumers can investigate issues such as the effectiveness of different drugs, side/adverse effects of medications, and new/alternative treatments among others<sup>12</sup>. In some cases patients are also able to check and verify the advice and treatment they receive from their doctors<sup>13</sup>;
- *Privacy and anonymity.* Consumers buying online can ask questions regarding medications and treatments which they may otherwise be embarrassed to ask in a public place<sup>14</sup>;
- *Generally cheaper costs.* Some studies have found that US residents import drugs into the US from Canada, due to lower prices which can be up to 70% cheaper<sup>15</sup>;
- *Availability of alternative treatments.* The licensing of drugs can a very slow process (due to testing requirements) but the Internet can facilitate access to effective non-licensed drugs that patients with terminal illness (e.g. Cancer, AIDS) may be willing to use on an experimental basis. This however, may not always be a benefit since there are many fraudulent treatments and drugs available online.

Concerns include:

- *Online prescriptions without prior physical examination by a doctor.* Some Internet Pharmacies use online consultations (questionnaires) to issue prescriptions to dispense drugs. There are many risks associated with this practice such as: the potential for misdiagnosis or drug interaction (among other problems) due to the lack of a physical examination,<sup>16</sup> the possibility of prescribing medications on false information; the possible absence of a legitimate (or licensed) consulting physician to evaluate the online

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<sup>10</sup> C.E. George, Online healthcare – Internet Pharmacies may not be good for your health. IFIP WG 9.2 Conference on Landscapes of ICT and Social Accountability. June 27-29, 2005. University of Turku, Turku, Finland.

<sup>11</sup> Consumer advice: buying drugs online. Harv Health Lett. June 2000; 25: 1-3.

<sup>12</sup> J. Henney, Cyberpharmacies and the role of the US Food and Drug Administration. J Med Internet Res. 2001; 3(1):E3

<sup>13</sup> A study reported in the British Medical Journal, 6 March 2004 (p564) concluded that some cancer patients were able to use the Internet verify their treatment and advice, which helped them to better understand their illness.

<sup>14</sup> Fung, C, Woo, H and Asch, S, Controversies and legal Issues of Prescribing and Dispensing Medicines Using the Internet. Mayo Clinic proc. 2004; 79: 188-194

<sup>15</sup> M. Korcok, Internet Pharmacy: the tug-of-war intensifies. JMAC, 16 March, 2004.

<sup>16</sup> J, Henny, Online Pharmacies – Maintaining the Safety Net. Medscape Pharmacists 1(1), 2000.

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questionnaire; loss of confidentiality; and difficulty in establishing duty of care (liability) as obtains in a traditional doctor–patient relationship<sup>17</sup>.

- *Dispensing prescription drugs without a prescription.* Some of the risks with this practice include: self-misdiagnosis; obtaining unsuitable drugs; and gaining addiction to drugs.<sup>18</sup>
- *Purity and quality of drugs.* Some online drugs can be either: past their expiry date; counterfeit<sup>19</sup>; sub-potent; or above potency. Further, drugs may be contaminated in storage or during shipping. It is also difficult to ascertain the origin of drugs bought online. For example, a US study found that many drugs which were claimed to be manufactured under FDA guidance or sent from Canadian pharmacies were manufactured in other countries such as China, Pakistan, Thailand, India, Iran and Singapore.<sup>20</sup> The quality of drugs is an important issues, since drugs of questionable quality can be harmful or may be ineffective for treatment leading to the worsening of a medical condition.
- *Foreign labels and different drug names.* A drug may have different names in different countries<sup>21</sup>. Countries also have different labelling requirements and dosage instructions<sup>22</sup>. This can lead to market confusion and consumers obtaining the wrong drugs.
- *Differences in drug classification.* The same drug may be classified differently in different countries.<sup>23</sup> This may mean that a prescription drug in one country may be purchased as an over-the-counter (not requiring a prescription) drug in another country.
- *Availability of unapproved or illegal substances & fraudulent products.* Many unapproved substances are marketed on the Internet. These include: narcotic<sup>24</sup>, psychotropic<sup>25</sup> and designer drugs<sup>26</sup>; ‘miracle cures’ and fraudulent treatments<sup>27</sup>. These substances can cause harm and can be costly.
- *Medical and financial privacy concerns.* Many Internet Pharmacies (especially in the US) do not adhere to their assurances on privacy and confidentiality<sup>28</sup>, and some have no

<sup>17</sup> S. Kahan, A. Seftel and M. Resnick, Sildenafil and the Internet. *The Journal of Urology*. Vol. 163, 919-923, March 2000.

<sup>18</sup> In 2001, a young UK (London) male drug abuser committed suicide after suffering from addiction to drugs bought online. At one point he was receiving 300 anti-depressant tablets in the post every day at his East London home and had tried 23 types of prescription drugs. See: A. Barnett, Deadly cost of the trade in online prescription drugs. *The Observer* Sunday August 10, 2003.

<http://observer.guardian.co.uk/drugs/story/0,11908,1015880,00.html>

<sup>19</sup> In 2003 The FDA estimated that 10% of the global medicines market was counterfeit and that over US\$32 Billion was being earned annually from the sale of counterfeit and substandard medicines.

[http://www.who.int/mediacentre/factsheets/2003/fs275/en/](http://www.who.int/mediacentre/factsheets/fs275/en/)

<sup>20</sup> *Giuliani Partners LLC, Examination and Assessment of Prescription Drug Importation from Foreign Sources to the United States. Interim Findings*, May 11, 2004. <http://www.heartland.org/pdf/14978.pdf>

<sup>21</sup> For example an ulcer medication named Prilosec in the US is sold as Losec in Canada.

<sup>22</sup> The US and Canada have slightly different dosage instructions for the anticonvulsant drug called Dilantin.

<sup>23</sup> Drug Classification: Prescription and OTC drugs, background. PAHO publication:

<http://www.paho.org/english/ad/thse/ev/CM-Background.pdf>

<sup>24</sup> Narcotic drugs are those which produce numbness or stupor. They are often taken for pleasure or to reduce pain, and prolonged use can lead to addiction (e.g. Cocaine).

<sup>25</sup> Psychotropic drugs affect the mind or mood or other mental processes e.g. Diazepam (Valium)- a sedative and muscle relaxant; Alprazolam (Xanax)- an anti-anxiety agent. These drugs are controlled under The United Nations Convention on Psychotropic Substances, 1971.

<sup>26</sup> Designer drugs are derived from making minor alterations of approved drugs in an effort to circumvent legal restrictions. They are intended for recreational use to give hallucinogenic experiences. (e.g. KAT, Special K, Cloud 9, Sextasy- Viagra combined with Ecstasy). See: <http://northport.k12.ny.us/~nms/masih/desdrugs.html> and <http://ncaddoc.org/atod-pages/dsgnr-drugs.htm>

<sup>27</sup> Examples of claims: A cure for arthritis with a fatty acid derived from beef tallow, and a treatment for cancer and AIDS with a Peruvian plant derivative. See: *Buying Drugs Online: It's convenient and private, but beware of 'rogue sites'*. *FDA Consumer Magazine*. Jan-Feb 2000 [http://www.fda.gov/fdac/features/2000/100\\_online.html](http://www.fda.gov/fdac/features/2000/100_online.html)

<sup>28</sup> *Online Pharmacies Settle FTC Charges*. *FTC Report*, July 12, 2000.

privacy policy<sup>29</sup>. This raises the potential for misuse of personal, financial or medical information.

- *Direct to consumer advertising of prescription drugs.* While this practice is illegal in the UK it is legal in the US. Such advertising may have the effect of stimulating the use of prescription drugs and other inappropriate behaviour.<sup>30</sup>
- *Risks of buying drugs online.* These risks may include all of the issues raised above, as well as the possibility of non-delivery of drugs or confiscation of drugs during shipment.
- *Drug resistance.* An important concern is the widespread/global availability of some antibiotics (drugs used to fight infection caused by bacteria) via Internet Pharmacies. Indiscriminate use of antibiotics can lead to bacteria developing resistance/immunity to such drugs resulting in new and deadlier strains of bacteria (sometimes called 'superbugs'). For example, in the UK hospital deaths related to MRSA<sup>31,32</sup> infections (caused by resistance to commonly used antibiotics) have caused great alarm among the medical establishment. A 2004 news report claimed that deaths due to MRSA had risen 1400% in a decade<sup>33</sup>. In February 2005, experts found 17 strains of MRSA with varying degrees of immunity to various antibiotics<sup>34</sup>. Further a News report published in February 2006 stated that in the UK, "MRSA infection in 2003-2004 rose to 1,168, an increase of 22% on the previous year"<sup>35</sup>.

The concerns above make a compelling case for the effective regulation of Internet pharmacies to ensure that consumers are not adversely affected by illegal acts or practices. Since Internet Pharmacies are accessible to global consumers, they can have a global effect, and therefore a global approach to regulation is needed. This is perhaps even more relevant since currently there are many differences in regulatory frameworks for Internet Pharmacies in different jurisdictions. The next section will examine two major jurisdictions namely the United Kingdom (UK) and United States (US) to illustrate how, although some similarities in regulating Internet pharmacies exists, there are important differences. These differences impact on the operation of Internet Pharmacies and the behaviour of consumers in the two jurisdictions.

### 3. Comparing regulatory frameworks in the UK and US

This section will compare some aspects of the regulation of Internet Pharmacies in the UK and US with a view to discussing some similarities and differences. The aspects of regulation compared are: standards and authorisations; regulatory structure; personal importation policy; advertising of drugs; online prescribing of drugs; protection of personal data; and self-regulation.

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<http://www.ftc.gov/opa/2000/07/iog.htm>

<sup>29</sup> P. Wenske, Online Pharmacies put Privacy at Risk. The Kansas City Star. July 18, 2004.

[http://www.kansascity.com/mld/kansascity/news/consumer\\_news/9164250.htm](http://www.kansascity.com/mld/kansascity/news/consumer_news/9164250.htm)

<sup>30</sup> T. Bessell et al, Quality of global e-pharmacies: can we safeguard consumers? Eur J Clin Pharmacol (2002) 58; 567-572.

<sup>31</sup> Methicillin-resistant Staphylococcus aureus. See: <http://www.netdoctor.co.uk/diseases/facts/mrsa.htm>

<sup>32</sup> <http://www.link.med.ed.ac.uk/ridu/Mrsa.htm>

<sup>33</sup> Superbug MRSA deaths up 1400% in a decade

<http://www.medicalnewstoday.com/medicalnews.php?newsid=6167>

<sup>34</sup> Q&A: MRSA 'Superbugs': <http://news.bbc.co.uk/1/hi/health/2572841.stm>

<sup>35</sup> Deaths Linked To MRSA Rose Significantly In England And Wales:

<http://www.medicalnewstoday.com/healthnews.php?newsid=38291>

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### 3.1 Standards and Authorisations

The standards of pharmaceutical and medical practice are similar in both UK and US jurisdictions. All drugs are subject to safety and quality regulations. Pharmacists and medical practitioners are subject to regulatory control by government bodies and professional organisations. Both jurisdictions require a need for prescriptions to be issued by licensed practitioners and dispensed by licensed pharmacists.

In both jurisdictions, there are similar authorisations for pharmaceutical and medical practice, which involve licensing by appropriate government authorities (or their affiliated organisations). In the UK pharmacists and pharmacies must be registered with the Royal Pharmaceutical Society of Great Britain (RPSGB)<sup>36</sup>, and doctors with the General Medical Council (GMC)<sup>37</sup>. In the US, all pharmacies and pharmacists are required to be licensed in the (US) state where they are resident.<sup>38</sup> Furthermore over 40 states require that out-of-state US pharmacies (or non-resident pharmacies) need to be licensed or registered in their state (i.e. the non-resident state) if they are shipping prescription drugs to state residents.<sup>39</sup> All physicians practising in a US state are required to be licensed by that state. Each state has a State Medical Board that is responsible for regulating physicians according to state medical practice laws, investigating complaints, and upholding professional standards among other requirements. All State Medical Boards belong to a representative organisation called the Federation of State Medical Boards (FSMB)<sup>40</sup> committed to developing and promoting high standards of medical practice by physicians.

In the UK and US, the marketing and selling of medical products are subject to control through a system of licences. In the UK under Section 58, of the Medicines Act 1968 (as amended)<sup>41</sup> (MA), it is illegal to supply prescription drugs except through a registered pharmacist with a prescription issued by an appropriate practitioner.<sup>42</sup> Also UK-based pharmacies can only legally sell pharmaceutical products licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA)<sup>43</sup>. In the US, the Food and Drug Administration (FDA) is the main federal agency responsible for the regulation of online drug sales. It has jurisdiction over matters regarding interstate commerce, which includes the sale of prescription drugs either between states or through importation from outside the US. With regard to Internet pharmacies, the main body of legislation enforced by the FDA is the Federal Food, Drug and Cosmetic Act (FFDCA) 1938 (as amended)<sup>44</sup>. Under the FFDCA, new drugs introduced or delivered into

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<sup>36</sup> The RPSGB, is a regulatory and professional body founded in 1841, consisting of pharmacists in England, Scotland and Wales. It receives its authority from the Pharmacy Act 1954 and the Medicines Act 1968 (both as amended)

<sup>37</sup> The GMC (<http://www.gmc-uk.org/>) was established by the Medical Act 1983 (as amended) (<http://www.gmc-uk.org/about/default.htm>)

<sup>38</sup> US General Accounting Office. Internet pharmacies - Adding Disclosure Requirements Would Aid State and Federal Oversight. Washington, DC: October 2000. Publication GAO-01-69.

<sup>39</sup> Ibid

<sup>40</sup> <http://www.fsmb.org/>

<sup>41</sup> The original Medicines Act 1968 has been amended many times due to new policies and EU directives.

<sup>42</sup> This means a doctor, dentist or other person authorised to prescribe such as a nurse prescriber.

<sup>43</sup> <http://www.mhra.gov.uk/>

<sup>44</sup> [http://www.access.gpo.gov/uscode/title21/chapter9\\_.html](http://www.access.gpo.gov/uscode/title21/chapter9_.html)

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interstate commerce must be FDA-approved (21 USC Section 355)<sup>45</sup>. This means that drug manufacturers must meet various quality and safety standards, are subjected to inspections, and must comply with the FDA's Good Manufacturing Practice.<sup>46,47</sup> Further the shipment and storage of drugs need to be clearly documented and subject to inspection.<sup>48</sup> Even if a drug is approved in the US, a foreign version of the drug is generally not considered FDA-approved because FDA approval is manufacturer-specific, product-specific, and requires detailed information about the product<sup>49</sup> (listed in the Code of Federal Regulations<sup>50</sup>). Various other provisions of the FFDCA directly relate to the sale of drugs over the Internet. The FFDCA prohibits the introduction or delivery into interstate commerce of drugs that are: adulterated or misbranded; unapproved; or counterfeit (21 USC Section 331 (a), (d), (i)). Pharmacists are prohibited from dispensing prescription drugs without a valid prescription issued by a licensed practitioner (21 USC Section 353(b)(1)). Also pharmacists are prohibited from dispensing prescription drugs without proper labelling (21 USC Section 353(b)(2)).<sup>51</sup>

### 3.2 Regulatory structure

The regulatory structure impacting on Internet Pharmacies in the two jurisdictions have some differences mainly due to different political structures. In the UK, there is a centralised control by a national government that sets policy whereas in the US, control is shared among federal, state and professional bodies. The UK system is very reliant on state licensed self-regulation (e.g. GMC, RPSGB) and independent self regulation (e.g. BMA<sup>52</sup>). The US has many governmental bodies (e.g. federal agencies - FDA, FTC<sup>53</sup> and State Boards) enforcing legislation in addition to self-regulation (e.g. NABP<sup>54</sup>, FSMB, AMA<sup>55</sup>). The US regulatory structure creates conflict between individual states and the federal government. While individual US states can regulate pharmacies, pharmacists and medical practice, state legislators have limited powers to regulate activities which impact on interstate commerce. The Commerce Clause of the United States Constitution,<sup>56</sup> gives the federal government the power to regulate interstate trade, and therefore makes any state legislation which affects interstate

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<sup>45</sup> The FFDCA is otherwise known as Title 21 of the United States Code (21 USC).

[http://www.access.gpo.gov/uscode/title21/chapter9\\_.html](http://www.access.gpo.gov/uscode/title21/chapter9_.html)

<sup>46</sup> The Good Manufacturing Practice requirements are detailed in the Quality System Regulation (passed into law by the FFDCA Section 520) and contained in Title 21. Part 820 of the Code of Federal Regulations (CFR).

<http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=199921>

<sup>47</sup> National Association of Boards of Pharmacy, Position Paper on the Importation of Foreign Prescription Drugs, March 2003. <http://www.nabp.net/ftpfiles/NABP01/foreigndrug.pdf>

<sup>48</sup> Ibid

<sup>49</sup> Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA to Robert P. Lombardi Esq., February 2003, <http://www.fda.gov/ora/import/kullman.htm>

(21 CFR Section 314.50). [http://www.access.gpo.gov/nara/cfr/waisidx\\_99/21cfr314\\_99.html](http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr314_99.html)

<sup>51</sup> A label is required to contain the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription.

<sup>52</sup> The British Medical Association (BMA), is a voluntary association founded in 1832, consisting of doctors practising in the UK <http://www.bma.org.uk/>

<sup>53</sup> The Federal Trade Commission (FTC) is a US federal agency primarily responsible for protecting consumers from fraud, deception and unfair business practices. <http://www.ftc.gov/>

<sup>54</sup> The National Association of Boards of Pharmacy (NABP) is an independent professional association established in 1994, consisting of member Boards of Pharmacy of all 50 States and some other jurisdictions.

<sup>55</sup> The American Medical Association (AMA), founded in 1847, is the national professional organisation for all physicians. It functions as an advocate for both patients and physicians. <http://www.ama-assn.org/>

<sup>56</sup> Article 1, Section 8, Clause 3

commerce unconstitutional. This creates difficulty for US States to effectively control some activities related to Internet Pharmacies.

### 3.3 Personal importation policy

Regulatory provisions regarding the importation of drugs for personal use have some differences in the two jurisdictions and hence different implications. The UK allows individuals to import medicinal products (except controlled drugs)<sup>57</sup> for personal or family use (MA, Section 13) without needing authorisation or a licence. Controlled drugs are listed in the Misuse of Drugs Act 1971 (as amended) and includes some prescription drugs. However, not all prescription drugs are on the controlled drugs list. In the US, however the FDA only allows personal importation under very strict conditions. Under the FDA's 'personal importation' policy,<sup>58</sup> a patient or his doctor is allowed to import a small amount of an unapproved drug into the US, from another country, under certain conditions. The conditions are that:<sup>59</sup>

- the patient must have a serious condition for which an effective treatment is not available in the US;
- the drug must not present an unreasonable risk;
- the drug must not have been commercially promoted to US residents;
- the patient seeking to import the product must affirm in writing that it is for his/her own use (not more than 3 months supply);
- the patient must give the name and address of the US doctor responsible for treatment with the unapproved drug or show evidence that the unapproved drug is used to continue a treatment started in a foreign country.

The 'personal importation' policy does not cover foreign versions of FDA-approved drugs, therefore under the FFDCA it is illegal for US residents to buy such foreign drugs on the Internet. The controls in the US are more rigid than in the UK, since US citizens cannot import drugs that are already marketed in the US. Citizens in the UK, however, are not restricted from importing drugs (for personal use), except where a drug is on the controlled drugs list.

### 3.4 Advertising of Prescription drugs to the public

The advertising of prescription drugs to the general public is illegal in the UK under the Medicines (Advertising) Regulations 1994 (as amended).<sup>60</sup> However, in the US, the First Amendment to the US Constitution generally protects the advertising of prescription drugs (directly to the public) as a form of commercial speech.<sup>61</sup> The legality of any advertising

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<sup>57</sup> Section 3, Misuse of Drugs Act 1971. <http://www.ukcia.org/pollaw/lawlibrary/updatedMoDA1971.html> .

Individuals wishing to import controlled drugs for personal use may need to get a licence. This however may be subject to the amount of the controlled drug imported: [http://www.britainusa.com/faq/guide\\_for\\_clinics.doc](http://www.britainusa.com/faq/guide_for_clinics.doc)

<sup>58</sup> FDA, Coverage of Personal Importations. [http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9pers.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html)

<sup>59</sup> Ibid

<sup>60</sup> UK Statutory Instrument 1994/1932, [http://www.legislation.hmso.gov.uk/si/si1994/Uksi\\_19941932\\_en\\_2.htm](http://www.legislation.hmso.gov.uk/si/si1994/Uksi_19941932_en_2.htm)

<sup>61</sup> L, Walters, Legal Issues Associated With Online Pharmacies. April 2004, PillLaws.com

<http://www.ainews.com/Archives/Story6548.phtml>

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regulation is subject to the *Central Hudson Test*<sup>62</sup>, and it has been difficult for the Federal Government to regulate the advertising of prescription drugs to the same extent that it has regulated the distribution of prescription drugs.<sup>63</sup> In an effort to tighten advertising requirements in January 2004, the FDA released new draft guideline proposals for direct-to-consumer drug advertising which encourages greater disclosing of risk information to consumers.<sup>64</sup>

With regard to advertising, Internet Pharmacies located outside of the UK (such as in the US) can circumvent UK law by advertising prescription drugs to UK residents. This difference in regulation can exacerbate the problems which UK regulatory authorities face when trying to control access to drugs from Internet Pharmacies<sup>65</sup>.

### 3.5 Online Consultations and Prescribing

In both jurisdictions, regulators have issued guidelines to address the practice of issuing prescriptions online. This practice is not seen as consistent with good medical care and is not encouraged in either jurisdiction. There are however, subtle differences in the scope of regulation of this practice for each jurisdiction.

The UK has taken a more relaxed attitude to this issue (compared to the US), although there has been one case of suspension of a doctor for conduct related to prescribing online<sup>66</sup>. In the UK Medical guidance given by the GMC does not expressly prohibit remote (online, email, telephone, video link) prescribing but instead gives doctors guidelines according to particular circumstances. Specific guidelines are given where the doctor: has responsibility for the patient; is deputising for the patient's doctor; or has prior knowledge and understanding of the patient's condition(s)/medical history, and is authorised to access the patient's records.

In addition, where a doctor is not providing continuing care to a patient, or does not have a patient's medical records, or is not deputising for the patient's doctor, the following guidelines are given:

- “Give an explanation to the patient of the processes involved in remote consultations and give your name and GMC number to the patient;
- Establish a dialogue with the patient, using a questionnaire, to ensure that you have sufficient information about the patient to ensure you are prescribing safely;
- Make appropriate arrangements to follow the progress of the patient;
- Monitor the effectiveness of the treatment and/or review the diagnosis;

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<sup>62</sup> “*Central Hudson*’s four-part test [to analyse commercial speech regulation] asks (1) whether the speech at issue concerns lawful activity and is not misleading and (2) whether the asserted governmental interest is substantial; and, if so, (3) whether the regulation [in question] directly advances the governmental interest asserted and (4) whether it [the regulation] is not more extensive than is necessary to serve that interest.” See: <http://www.law.cornell.edu/supct/html/98-387.ZS.html>

<sup>63</sup> See note 54

<sup>64</sup> <http://www.fda.gov/cder/guidance/5669dft.doc>

<sup>65</sup> Note that some US prescription drugs may be classed as controlled drugs in the UK and therefore UK individuals are prohibited from importing them for personal use without authorisation.

<sup>66</sup> In January 2002 Dr Richard Franklin was found guilty of serious professional misconduct by the GMC after prescribing drugs online. The GMC found that he did not carry out an adequate assessment of his patients' conditions, and therefore did not act in the best interests of his patients. BBC News, Viagra web doctor suspended. 10<sup>th</sup> January 2004. <http://news.bbc.co.uk/1/hi/england/1752670.stm>

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- Inform the patient's general practitioner or follow the advice in Q3 [GMC advice on prescribing medicines] if the patient objects to the general practitioner being informed.”<sup>67</sup>

UK doctors are advised not to prescribe via remote means if the conditions set out in the GMC guidance documents are not satisfied.

In the US, various regulatory bodies have issued guidelines for prescribing via the Internet. These include the FSMB (Federal State Medical Boards) guidelines of 2002<sup>68</sup> and the American Medical Association (AMA) guidelines of 2003<sup>69</sup>. The US guidelines and regulatory approach go further than in the UK. In the US, the guidelines insist that a prescriber/practitioner must have a qualifying medical relationship with the patient at the time of issuing a prescription (The AMA guidelines makes an exception where a doctor is in consultation with the patient's doctor). Such a relationship entails conducting a face-to-face physical examination of the patient and having knowledge of the patient's medical history. This implies that in the US a doctor is only legally entitled to prescribe online, if he has already carried out a physical examination of the patient and knows the patient's medical history (or is consulting with the patient's doctor), a policy which is different to the UK position. In addition to the above, in February 2005, the “The Ryan Haight Act” was introduced in the US Congress to address ‘rogue pharmacies’ especially to prevent Americans from obtaining drugs without a prescription (or with a prescription based solely on an online questionnaire).<sup>70</sup>

### 3.6 Protection of Personal Data

Internet Pharmacies based in the US are more likely to violate privacy protection requirements compared to those based in the UK. In the UK the Data Protection Act 1998<sup>71</sup>, stipulates legal requirements to ensure that personal data collected on consumers are safeguarded from abuse and remain confidential. It plays a role in regulating Internet pharmacies, in terms of stipulating controls for the processing, storage and transfer of personal data collected during online transactions. In the US however, there is no strong culture of privacy and data protection legislation. The US takes a sector based approach to privacy which consists of mixed legislation, regulation and self-regulation.<sup>72</sup>

### 3.7 Self-Regulation/Certification

In both the UK and US, some degree of self-regulation/certification exists, however, the extent to which this is done remains questionable. In the UK medical websites can apply for HONcode accreditation to display the HONcode seal<sup>73</sup> which signifies a pledge to respect and honour the 8 principles of the Health on the Net Foundation Code of Conduct<sup>74</sup>. Legitimate Internet Pharmacies in the UK must register their premises with the Royal Pharmaceutical

<sup>67</sup> [http://www.gmc-uk.org/guidance/library/prescriptions\\_faqs.asp](http://www.gmc-uk.org/guidance/library/prescriptions_faqs.asp)

<sup>68</sup> Model Guidelines for the Appropriate use of the Internet in Medical Practice. Accessed via the FSMB homepage: [http://www.fsmb.org/pdf/2002\\_grpol\\_Use\\_of\\_Internet.pdf](http://www.fsmb.org/pdf/2002_grpol_Use_of_Internet.pdf)

<sup>69</sup> H-120.949 Guidance for Physicians on Internet Prescribing: Accessed via the AMA website:

[http://www.ama-assn.org/apps/pf\\_new/pf\\_online?f\\_n=browse&doc=policyfiles/HnE/H-120.949.HTM](http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-120.949.HTM)

<sup>70</sup> <http://www.senate.gov/~feinstein/05releases/r-internet-pharm.htm>

<sup>71</sup> <http://www.data-protection-act.co.uk/>

<sup>72</sup> US General Accounting Office. Internet pharmacies - Adding Disclosure Requirements Would Aid State and Federal Oversight. Washington, DC: October 2000. Publication GAO-01-69.

<sup>73</sup> Use of the HONcode seal. <http://www.hon.ch/HONcode/>

<sup>74</sup> The 8 principles of the HONcode address: Authority, Complementarity, Confidentiality, Attribution, Justifiability, Transparency of authorship, Transparency of sponsorship, and Honesty in advertising & editorial policy: <http://www.hon.ch/HONcode/Conduct.html>

Society of Great Britain (RPSGB), and are listed on the RPSGB online register<sup>75</sup>. The US regulatory model provides a means for Internet pharmacies to self-certify themselves, for example, via the Verified Internet Pharmacy Practice Sites (VIPPS) program<sup>76</sup>. The VIPPS program confers the VIPPS-certification on Internet pharmacies which comply with licensing and inspection obligations in its resident state and in all states where it dispenses medication. An internet pharmacy displaying a VIPPS seal publicly indicates that it adheres to certain VIPPS criteria including: respect for privacy rights; verification and security of prescriptions, meeting recognised quality assurance and providing meaningful consultation between patients and pharmacists. This enables consumers to have confidence that the pharmacy is bona fide, and that it adheres to certain standards and criteria. At the date of writing only 12 Internet Pharmacies are listed on the VIPPS online database.

#### 4. Some Reasons for Differences

The different frameworks in the two jurisdictions stem from historic, geographic, economic, and political differences.

From a historic perspective, Internet pharmacies are essentially an extension of mail-order pharmacies. Unlike the UK, the US has a long history of mail-order pharmacies. In fact the UK pharmaceutical profession is reported to have resisted mail-order pharmacies for the past 150 years.<sup>77</sup> This is because typical UK community pharmacies earn most of their revenue from dispensing medicines and mail-order pharmacies would have essentially processed large numbers of prescriptions from a central site, undermining the community pharmacy network.<sup>78</sup> In the US, before the advent of the Internet, many laws were in place to regulate mail-order pharmacies. Such laws were useful in focusing US legislative thinking on the relevant issues related to the distance selling of drugs. This is not the case in the UK as seen by the way in which UK authorities have viewed Internet Pharmacies in the past. In 2000, the Department of Health (DoH) did not appear to think that there was a problem in the UK, when called upon to crack down on illegal Internet prescriptions.<sup>79</sup> The DoH responded that the UK did not have a history of mail-order drug sales like the US, and that UK online pharmacies were required to have a prescription to dispense drugs.<sup>80</sup> This response was criticised by the BMA as being a naive view and a failure to grasp the fundamental issue, that Internet pharmacies transcend geographic boundaries.<sup>81</sup>

Geographic differences between the two jurisdictions may account for the rate of growth of Internet Pharmacies within the respective jurisdictions, and hence the perception of the problems that they may pose. In the UK most people live within a short distance of a pharmacy. A 2003 OFT report concluded that seventy-nine percent (79%) of people in the UK live within 1 kilometre of a pharmacy and forty-seven percent (47%) have a pharmacy within 500

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<sup>75</sup> Buying Medicines over the Internet: MHRA website:

[http://www.mhra.gov.uk/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodeId=254](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=254)

<sup>76</sup> Verified Internet Pharmacy Practice Sites™ (VIPPS) program: <http://www.nabp.net/vipps/intro.asp>

<sup>77</sup> The Implications of e-commerce for community pharmacy. The Pharmaceutical Journal Vol 265 No 7118, page 580. Plenary session, October 14 2000

<sup>78</sup> Ibid

<sup>79</sup> BBC News, Crackdown on Internet Prescriptions, Sat 27<sup>th</sup> May 2000.

<http://news.bbc.co.uk/1/hi/health/765117.stm>

<sup>80</sup> Ibid

<sup>81</sup> Ibid

metres.<sup>82</sup> In the US remoteness has been cited as a major reason for consumers using Internet pharmacies.<sup>83</sup> This therefore suggests that the comparatively smaller size of the UK with less inaccessible regions compared to the US have meant a smaller market demand for distance selling of medicines in the UK. The effect of this may be that regulators in the UK perhaps until lately have not been very focused on the potential problems that Internet pharmacies may pose, especially those not located within the UK jurisdiction.

From an economic perspective, the provision of medical services in the UK is completely different to the US. The UK has a single dominant state run National Health Service (NHS) largely funded by taxation. Medical services (and doctors) are free and the NHS generally provides free or subsidised medicines depending on the circumstances of the patient. In the US there is no single healthcare system, but rather a pluralist system, driven by the state and also by markets.<sup>84</sup> Medical services are funded privately or by private insurance, federal Medicare or state Medicaid.<sup>85</sup> Most doctors are self employed and the cost of consulting a doctor is generally high.<sup>86</sup> Unregulated drug prices and strong patent laws have resulted in high drug costs (compared to its neighbour Canada where regulated prices and weaker patent laws have meant comparatively lower costs). The economic imperative to seek cheaper sources of drugs has therefore increased the popularity of Internet Pharmacies. This popularity may have contributed to the US regulatory authorities being more acutely aware of potential regulatory issues and hence shaping their regulatory policies accordingly. This may perhaps further explain two of the differences raised previously: (i) The direct-to-consumer advertising of prescription drugs in the US may have the beneficial effect of informing patients about drugs and empowering them to seek cheaper medications either from their doctors or dispensing pharmacies; (ii) the tighter controls on Internet prescribing in the US may be due to the high demand for such online services because of the high costs of consulting a US doctor.

Different political cultures in the UK and US may account for regulatory differences. In the US the influence of interest groups and reactions to various national medical disasters such as: Sulfanilamide (1937), Thalidomide (1961) and AIDS (1980s), have significantly shaped US regulatory policy.<sup>87</sup> Political pressure for change to address these disasters (especially from interest groups) led to government action in passing legislation and instituting strong regulatory controls. For example, the strict legal rules prohibiting the importation (into the US) of drugs that are not FDA-approved may be explained by the presence of a more protectionist political culture, resulting from a fear of unsafe medicines entering the US, bearing in mind previous medical disasters. In the UK, however, change has been instituted by a more consensus-based political culture which is driven by scientific and medical experts.<sup>88</sup>

## 5. A Global approach is needed

The preceding sections highlight the many problems that may arise with Internet Pharmacies and by extension bring regulatory challenges to authorities. These challenges are compounded

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<sup>82</sup> UK Office of Fair Trading(2003).

<http://www.offt.gov.uk/NR/rdonlyres/BABF839A-3088-4EBB-B3A9-00D955719EE0/0/oft609.pdf>

<sup>83</sup> Consumer advice: buying drugs online. Harv Health Lett. June 2000; 25: 1-3.

<sup>84</sup> M, Moran and B, Wood, States, Regulation and the Medical Profession, 1993. Open University Press.

<sup>85</sup> Ibid

<sup>86</sup> Ibid

<sup>87</sup> A, Daemrich, Regulatory Laws and Political Culture in the United States and Germany in J, Abraham and H, L, Smith (Eds), Regulation of the Pharmaceutical Industry, 2003.

<sup>88</sup> Ibid

by the nature of the Internet itself and the existence of different regulatory structures in various jurisdictions, as demonstrated by the examples of the UK and US. These differences imply a lack of a global approach to tackle various illegal acts carried out by some Internet Pharmacies. Enforcement of regulatory rules is mainly possible within a legal jurisdiction and businesses which operate outside the scope of that legal jurisdiction present difficult problems to regulators. The nature of the Internet means that residents of one state/country are exposed to global online commerce, except where country-specific filtering software is used to block certain sites (from outside the jurisdiction). Internet filtering is not in widespread use for commercial Internet activity in Western countries (such as the UK and US) as seen in other jurisdictions like China and Singapore. It is also unlikely that the democratic ethos of the UK and US will tolerate the censoring of commercial activity on the Internet.

It is difficult or impossible for regulatory bodies to control advertising of prescription drugs from Internet sites beyond their legal jurisdiction. This is especially true for the UK where national rules prohibit the advertising of prescription drugs to the public unlike in the US. It is highly unlikely, however that the advertising of prescription drugs will ever be made illegal in the US, due to fact that it is constitutionally protected. This therefore will continue to create a challenge to regulators in jurisdictions where the advertising of prescription drugs (to the public) is prohibited.

Tracing web site servers which may be mobile or located in certain countries presents a major challenge to regulators. Owners of such websites will continue to engage in regulatory arbitrage<sup>89</sup> and hence evade enforcement actions in countries like the UK and US that have high regulatory standards.

The need for a global approach to address drug sales on the Internet (especially Internet Pharmacies engaging in illegal activity) is indeed compelling in light of the preceding discussions. The use of a global approach to address matters which are of global significance has been successfully implemented in the past. For example UNCITRAL<sup>90</sup> has a mandate from the United Nations to progressively harmonise and unify the law of international trade (hence reducing or removing obstacles to the flow of trade due to disparities in national laws). UNCITRAL Model Law on areas such as 'electronic signatures', 'electronic commerce', and 'international credit transfers' have resulted in the harmonisation of laws (affecting international trade) across nation states. It must be noted that the regulation of Internet Pharmacies is more complex (than the latter examples) and some may argue that it is difficult or undesirable to regulate Internet-based entities (that transcend national boundaries). Nonetheless, nation states can begin to harmonise their laws, have cooperative agreements, and develop new institutions/organisations to collectively address the concerns that Internet Pharmacies bring. Technological solutions (where possible) and public education programs can also be implemented at national levels.

A global approach can include a UN-lead programme (possibly by the World Health Organisation–WHO) to develop international agreements, and help harmonise national legislation to result in common policies (that reflect international standards) on areas such as: online medical consultations (without a physical examination by a doctor); online prescribing;

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<sup>89</sup> M, Fromkin. *The Internet As A Source Of Regulatory Arbitrage*, 1996  
<http://www.law.miami.edu/~froomkin/articles/arbitr.htm>

<sup>90</sup> The United Nations Commission on International Trade Law: <http://www.uncitral.org/uncitral/en/about/origin.html>

the advertising of prescription drugs to the public; the certification of medical websites; the naming of drugs and dosage instructions; the classification of drugs, especially prescription drugs; and the hosting (by Internet Service Providers) of pharmacies (and other websites) involved in illegal activities.

## **6. Conclusion**

Although the Internet continues to bring many benefits to the global community, the widespread availability of drugs and medical services via the Internet (especially through illegal activity) has the potential to result in problems of a global nature. Examples of such problems include: widespread drug addiction which may have consequences for the wider society; harm (or death) from drugs that may be contaminated, counterfeit, sub-potent or above potency; the development of new strains of bacteria (and hence new diseases) due to indiscriminate use of antibiotics; and increased criminal activity related to illegal medical practice and the supply of drugs; These potential problems are further compounded by the inability of nation states to effectively control websites not located within their physical jurisdiction. There is a pressing need for nation states to develop a global approach/strategy to collectively address the issue of online drugs and medical services. This global approach/strategy should entail cooperative agreements (e.g. for enforcement), and the harmonisation of national policy and legislation, to reflect internationally agreed standards. Failure to address this problem may result in serious consequences (in the future) for the health and well-being of the global community.