

## Chapter I

# Online Medical Consultations: Legal, Ethical, and Social Perspectives

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### Abstract

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*The growth of the Internet over the last 10 years as a medium of information and as a communication technology has provided the opportunity for selling medical products and services online directly to the public. This chapter investigates on-line medical consultations used for the purpose of prescribing and hence selling prescription drugs via the Internet. With consumers in mind, this chapter takes a critical look at this growing phenomenon from three perspectives—legal, ethical, and social—as a basis for discussion and to illustrate the problems raised by using the Internet in this way. The chapter concludes that online medical consultations pose greater dangers to patients compared to traditional off-line consultations. The chapter also concludes that while new technologies may aid doctors in making better diagnoses at a distance, they often bring new concerns. Finally, the chapter gives suggestions on safeguarding online consumers.*

## Introduction

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The growth of the Internet over the last 10 years as a medium of information and as a communication technology has, not unsurprisingly, provided a foundation for the growth of direct-to-the-public online sales. Amongst the many commercial activities that are now flourishing in this environment are Internet pharmacies (e-pharmacies, cyber pharmacies), providing a variety of products (e.g., health and beauty products) as well as prescription drugs. Some pharmacies only dispense drugs with a valid prescription, some provide online consultations for prescribing and dispensing medicines, and some dispense medications without a prescription (Radatz, 2004).

Internet pharmacies provide various benefits to consumers but also bring many problems for regulators and consumers (George, 2005). Benefits include the ease and convenience of 24-hour shopping, increased consumer choice of products, increased consumer information, and information exchange between patient and pharmacist, generally lower costs, privacy, and availability of alternative treatments. Problems include uncertainty about the purity and quality of drugs sold, risks of buying drugs online, for example, related to foreign labels and use of different drug names in different countries, dispensing prescription drugs without a prescription, and the issuing of prescriptions through online consultations but without prior physical examination by a licensed physician. This latter aspect provides the focus of this chapter.

The chapter will first discuss online consultations, identifying various concerns. It will then discuss the various legal, social, and ethical issues related to this growing practice. The role of information technology both in terms of creating such problems but also possibly facilitating solutions will be examined. Finally, the chapter provides some suggestions on how consumers can be safeguarded in the future.

## Online Medical Consultations

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Many Internet pharmacies provide online consultations as a first step towards selling prescription medicines online. These consultations usually require that a potential customer fill out an online questionnaire. A 2007 study by the U.S. National Centre of Addiction and Substance Abuse (CASA, 2007) concluded that:

- Between 2004 and 2006 there was an increase in the number of Internet pharmacies (not requiring prescriptions) offering an online consultation: 2004—53% (76), 2005—57% (84), and 2006—58% (90);

- In 2007, of the 187 sites that offered to sell controlled prescription drugs over the Internet, 85% (157) did not require a prescription. Also, 53% (83) of the sites not requiring a prescription offered clients an online consultation.

A typical online consultation questionnaire may consist of three parts. The first part asks for personal details such as name, address, contact telephone numbers, date of birth, height, body weight, and gender. The second part of the questionnaire asks about medical history including whether a particular drug requested has been used before, what drugs are currently being taken, a history of allergies and side-effects to certain medicines, what complaint is the drug requested for, and whether the customer has suffered from a range of conditions such as heart disease, kidney disease, liver disease, diabetes, epilepsy, hypertension, asthma, and chronic bowel disorders. The third part asks for payment details and shipping information.

After the questionnaire is completed, it is then reportedly evaluated by a licensed physician/doctor affiliated to the pharmacy in order to either approve or decline a prescription request. If a request is approved, a prescription is written by the physician then sent to the pharmacy for dispensing and shipping of the medication. In addition to the medication, a customer will receive contact information for the pharmacy and information on usage, dosage, and precautions relating to the medication.

Consultations made online, by their very nature, do not involve a physical examination in person by a licensed physician. Therefore, they may be dangerous both in terms of making a correct diagnosis and determining drug interactions (Henney, 2000), amongst other problems discussed throughout the chapter.

In some cases, physicians/doctors who issue online prescriptions (“cyberdoctors”) are either not licensed to practice medicine in the consumer’s state/country or are not credible. A 2003 U.S. study reported that many cyberdoctors recruited by Internet pharmacies were previously unemployed, semi-retired, or had declining practice incomes (Crawford, 2003). Also, investigations into the backgrounds of some online prescribing physicians have found that some had previous convictions for either forgery, fraud, or sexual assault, revoked or suspended licences, and addiction to drugs or alcohol (BDA, 2004).

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## Legal, Ethical, and Social Perspectives

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In the following pages, the practice of online medical consultations is looked at from the three different perspectives: legal, ethical, and social. In a context of use, it can often be difficult to distinguish between these three. Although legal aspects should be more easily identifiable (through citizens’ familiarity with law), there are particular laws that are applicable to specific situations and domains—as in this

case. Similarly, non-experts in ethics can often recognise some ethical difficulties but may confuse ethical with social issues. The different aspects are discussed in this chapter under the relevant headings, but some explanation of the differences may be helpful at this point.

Activities within public life necessarily have an impact on other people that may be beneficial or harmful. Benefits and harms are determined according to the values of the people within a society, and come under the domain of ethics. The rules governing social activities, and which promote benefits and prevent harm, are formally expressed in legislation, and less formally in, for example, professional codes of conduct, or practice. Thus legislation formally upholds social values (within democratic societies at least) and in this way supports the ethical position of that society. However, not all “bad” actions are regulated by law, and not all laws are necessarily ethical. Ethics is a complex subject, but one could say that the “laws” of ethics are expressed as ethical principles, which are used in this chapter to give a reference point for discussion. Finally, the social perspective is a broader perspective that looks at society as a whole (rather than individuals within society). This perspective is needed to see the “bigger picture”—that is the application of a technology within society and the impact that it is likely to have.

Thus an assessment of the benefits and harms of a new technology on individuals and the general public can be done by using a framework that refers to the law (formal social rules guiding behaviour), ethical principles (personal and social views of behaviour), and social aspects.

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## The Legal Perspective

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### Regulation in the UK and U.S.

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Online consultations are an important first step in aiding patients to legally purchase prescription drugs online. In both the UK and U.S., drugs classified as “prescription drugs” require a prescription issued by an appropriate licensed healthcare professional before such drugs can be dispensed by a pharmacist. In the UK, the Medicines Act 1968 (as amended), classifies medicines into three classes namely: (1) Prescription only (Section 58), which can only be sold with a valid prescription; (2) Pharmacy only (Section 60), which must be sold in consultation with a pharmacist; and (3) General Sales List (Section 5), which do not require any prescription or consultation before sale. Under Section 58, it is illegal to supply prescription only drugs except through a registered pharmacist with a prescription issued by an appropriate practitioner. In the U.S., under the Federal Food, Drug, and Cosmetic Act (i.e., Title 21 of the United States Code – 21.U.S.C.), drugs are classified into two categories

namely: prescription drugs and over-the-counter drugs. Under 21.U.S.C.353(b)(1), pharmacists are prohibited from dispensing prescription drugs without a valid prescription issued by a licensed practitioner (physician). Over-the-counter drugs do not require a prescription for sale.

As noted earlier, online consultations are an important aspect of the online selling of prescription drugs since these consultations are used to issue prescriptions to enable the sale of drugs. All medical consultations, however, are subject to certain professional standards, and in many instances consultations done online fall below the accepted professional standards (of a medical consultation) as set out in the regulation of medical practice.

In the UK, medical practice is regulated by the General Medical Council (GMC) and to some extent the British Medical Association (BMA). The GMC was established by the UK Medical Act 1983 (as amended) and its primary functions are “to protect, promote, and maintain the health and safety of the public” (Section 1). All doctors practising medicine in the UK must be registered with the GMC. Registration involves the granting of various privileges (e.g., the right to prescribe drugs, access to medical records, authority to sign medical certificates) and obligations (e.g., confidentiality, adherence to code of practice). Under Section 36, the GMC has the authority to suspend or remove from the register any fully registered person found guilty of professional misconduct or convicted of a criminal offence (even if not committed in the UK). In 2004 the General Medical Council (GMC) issued new practice guidelines (further revised in 2006) which detail conditions to be met for remote prescribing (via telephone, e-mail, fax, video, or Web site) in situations where a doctor: (a) has responsibility for the care for a patient, (b) is deputising for another doctor responsible for the care of a patient, or (c) has prior knowledge and understanding of the patient’s condition and medical history and has authorised access to the patient’s medical records (GMC, 2006, paragraph 38). If these situations are present, the doctor is advised that he or she must have an appropriate dialogue with the patient to:

- “Establish the patient’s current medical conditions and history and concurrent or recent use of other medications including non-prescription medicines;
- Carry out an adequate assessment of the patient’s condition;
- Identify the likely cause of the patient’s condition;
- Ensure that there is sufficient justification to prescribe the medicines/treatment proposed. Where appropriate you should discuss other treatment options with the patient;
- Ensure that the treatment and/or medicine/s are not contra-indicated for the patient;

- “Make a clear, accurate, and legible record of all medicines prescribed.” (GMC, 2006, paragraph 39)

In the absence of situations (a) to (c) discussed above the GMC does not expressly forbid remote prescribing but gives additional conditions, which a doctor must satisfy if remote prescribing is to be used. The prescribing doctor is advised of the additional conditions as follows:

- “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;
- Inform the patient’s general practitioner or follow the advice in paragraph 9 if the patient objects to the general practitioner being informed.” (GMC, 2006, paragraph 40)

Paragraph 9 states that:

*If the patient does not want their general practitioner to be informed, or has no general practitioner, then you must: (a) Take steps to ensure that the patient is not suffering from any medical condition or receiving any other treatment that would make the prescription of any medicines unsuitable or dangerous or (b) Take responsibility for providing all necessary aftercare for the patient until another doctor agrees to take over. (GMC, 2006)*

The GMC guidelines give further advice to doctors if they prescribe for patients who are overseas. These include the need to be aware of differences in the licence names, indications and recommended dosage of medical products, the need to ensure adequate indemnity cover for such practice, and the need to be registered with the appropriate regulatory body in the jurisdiction where the prescribed medicines are to be dispensed.

In the U.S., all physicians/doctors practising within a 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 others. All U.S. state medical boards belong to a representative organisation called the Federation of State Medical

Boards (FGSMB) that is committed to developing and promoting high standards of medical practice by physicians. In 2002, the U.S. Federation of State Medical Boards published, *“Model Guidelines for the appropriate use of the Internet in Medical Practice”* (FSMB, 2002). Some of the guidelines specifically addressed the issue of remote prescription practices stating the need for “documented patient evaluation” (including a patient history and physical evaluation), and that “Issuing a prescription based solely on an online questionnaire or consultation does not constitute an acceptable standard of care” (FSMB, 2002). The FSMB Guidelines further state that “e-mail and other electronic communications and interactions between the physician and patient should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship.” (FSMB, 2002),

Guidelines issued by the American Medical Association in 2003 (regarding the prescribing of medicines to patients via the Internet) state that a physician who prescribes medications via the Internet must establish or have an established a valid patient-physician relationship (AMA, 2003). This includes among other things: obtaining a reliable medical history and performing a physical examination of the patient; having sufficient dialogue with the patient regarding treatment options, and risks and benefits of the treatment; and having follow-ups with the patient where appropriate. In the U.S., therefore, the use of an online questionnaire without a physical examination of a patient, will not amount to the existence of a legitimate patient-physician relationship. Indeed many U.S. States have passed laws which add prescribing without first conducting a physical examination to the definition of unprofessional conduct (e.g., Arizona Revised Statutes Title 32, Chapter 13 Article 1; California Business and Professions Code Section 2242 and 4067; Kentucky Revised Statutes 311.597(1)(e); Missouri Statute 334.100.2(4)(h); Nevada Revised Statutes 453.3611). A listing of the policies of state medical boards and state legislation regarding Internet prescribing can be found at FSMB (2007a).

In both the U.S. and UK, doctors have been prosecuted for using online consultations to prescribe drugs. For example, in the UK, Dr. Richard Franklin was found guilty of serious professional misconduct by the GMC after prescribing drugs online (BBC, 2002). Patients were required to fill out an online questionnaire, which was then reviewed by Dr. Franklin and used to prescribe drugs. The GMC stated that the questionnaire was closed and did not allow for a dialogue between doctor and patient. Also, that Dr. Franklin did not carry out an adequate assessment of his patients' conditions, and therefore did not act in the best interests of his patients (BBC, 2004). Regarding the U.S., details of the convictions (e.g., fines, suspensions) and other disciplinary actions (from 1998-2007) of numerous U.S. physicians for online prescribing are given at FSMB (2007b). A typical example is Dr. Shreelal Shindore of Florida (U.S.) who was forced to relinquish his medical license after “prescribing a Schedule IV controlled substance to a patient who completed an Internet ques-

tionnaire without conducting a physical examination, obtaining a complete history, making a diagnosis, or establishing a treatment plan” (NYSBPM, 2004).

One of the purposes of a professional medical body (or other professional body) is to provide protection for those seeking expertise, that is, those who are less expert and therefore vulnerable in their lack of knowledge (e.g., RPS, 2006; Duquenois, 2003). The case of Dr. Franklin illustrates this aspect where the GMC stated that Dr. Franklin did not act in the best interests of his patients. Whilst the law has taken action in this particular case, it may become increasingly difficult to monitor the activities of doctors practicing in this way—and in particular in areas where either no medical body exists, or where a medical body does not have the weight of established professional bodies such as the GMC in the UK, and FSMB in the U.S..

## **Liability for Patient Care**

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A person becomes liable if he or she fails to perform a legal obligation or duty. Such legal obligations or duties may arise from fiduciary relationships between parties, existing laws (statute, common law), or contractual agreements among others. Liability can be civil or criminal and can arise under various areas of the law such as professional malpractice, negligence, negligent misstatement, and breach of contract.

In the traditional doctor-patient relationship, if a patient suffers loss or damage caused by negligent or intentional acts committed by the doctor (in the course of performing his or her duties) then professional malpractice claims may arise. It may be the case however, that for online consultations, only civil liability issues may arise since liability for professional malpractice may not be clearly established where an online prescription is issued (Kahan, Seftel, & Resnick, 2000). This is because whereas in a traditional doctor-patient relationship a clear duty of care exists, it is debatable whether a doctor who prescribes medication online (without any direct verbal or physical contact with a patient), forms a traditional doctor-patient relationship and therefore attracts the same duty of care.

Although the same level of “duty of care” as in a traditional doctor-patient relationship may not exist in an online consultation, a prescribing doctor will still be required to exercise a duty of care to prevent loss or injury to a patient. A breach of that duty (e.g., through careless acts or omissions) leading to loss which is a direct and natural result of the breach (i.e., consequential loss) will result in liability for negligence. Where a prescribing doctor gives incorrect medical advice, which leads to loss, then liability for “negligent misstatement” may be established. For a breach in negligence, an injured patient can be awarded damages or compensation, and the prescribing doctor can incur financial and/or criminal penalties, depending on the seriousness of the breach.

Finally, a contractual relationship will exist between an online prescribing doctor and a patient, due to the fact that the patient is making payment for a service. Therefore, a prescribing doctor will be bound by his or her contractual obligations, which include express contractual terms as well as terms implied by law (e.g., regarding the quality of service). Failure to perform his/her contractual obligations will result in the prescribing doctor facing an action of breach of contract and possibly incurring a financial penalty.

## **Confidentiality and Data Protection**

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The writing of prescriptions via online consultations raises important legal issues of confidentiality and data protection. Confidentiality focuses on maintaining the secrecy of information and data protection focuses on the legal framework governing the processing (collection, storage, security, and use) of personal data.

During an online consultation, a patient places his or her trust in a prescribing doctor and in turn, the doctor has a duty to faithfully discharge his responsibility. It is therefore widely accepted in law that there exists a fiduciary (trust) relationship between doctor and patient because of the vulnerable position of the patient. By virtue of the fiduciary (trust) relationship that exists between an online prescribing doctor and a patient, the prescribing doctor will be under an obligation of confidence not to disclose any medical information divulged to him/her unless authorised to do so. Confidentiality issues may arise because information given for online consultations may be prone to be seen by people other than the consulting doctor, unless strict security and protocols are in place (Kahan et al., 2000). Staff assisting a prescribing doctor in the provision of medical care will most likely be authorised to have access to patients' medical data and therefore will also have an obligation of confidence. However, the transmission of data between doctor and patients over the Internet poses an inherent risk that such data may be accessed in transit by an unauthorised person. This has important implications within the European Union/United Kingdom (EU/UK) with regard to obligations under data protection law. In the EU/UK medical data is classified as "sensitive personal data" (Data Protection Act, 1998, Section 2(e)) and acknowledged as a special category (amongst others such as ethnic origin, religious belief) which requires a higher level of protection compared to ordinary personal data. Amongst eight data principles in the 1998 Act, the seventh principle states that "data must be kept secure from unauthorised access, unlawful processing, destruction, or damage" (Schedule I). This implies that online transactions must have adequate security to prevent the unauthorised access to medical data.

## **Jurisdiction**

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The Internet crosses geographic and state boundaries and hence creates a global market for commerce. It is thus relatively easy for a medical practitioner to be located within one jurisdiction and to administer an online consultation to a patient located in a different jurisdiction, without being licensed to practice medicine in either of the jurisdictions. The practice of medicine within any jurisdiction without an appropriate licence is a criminal offence, since it places citizens at a serious risk. It may, however, be difficult to successfully prosecute a medical practitioner located in a jurisdiction different to that of the patient. This is especially true where it is prohibitively expensive to do so or where the appropriate legal agreements between jurisdictions (especially countries) are not present.

In the European Union, all member states are signatories to the Brussels Regulation (i.e., Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction) and the recognition and enforcement of judgments in civil and commercial matters. This legal instrument details the rules for determining jurisdiction (i.e., which courts are entitled to adjudicate on an action) in EU states in matters of tort (civil wrongs) and contract law. As mentioned earlier, an online medical consultation may give rise to a legal action (e.g., a tort committed over the Internet), where a doctor makes a negligent misstatement such as giving incorrect medical advice. Under the Brussels Regulation, a patient can bring an action in tort against an Internet doctor (defendant) in the courts of the state where the doctor (defendant) is domiciled, or in the courts of the state where the harmful event occurred (i.e., the place where the wrongful action was carried out or the place where the damage occurred). Where the regulation does not apply (e.g., the defendant is not in an EU state or a criminal charge is contemplated), then various other rules (e.g., common law rules) may be used to determine jurisdiction.

## **The Ethical Perspective**

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The ethical issues are closely related to the legal concerns expressed above. In the cases reported in the previous section, national legislation serves to protect patients and uphold the established ethical practices of the medical profession. The foundation for the ethical principles of the medical profession (in the western world) is the Hippocratic Oath (Nova, 2001a). The principles referred to in the Hippocratic Oath recognise the responsibilities of the expert to those who seek their professional help, amongst which are prevention of harm, justice, respect for the person, and maintaining confidentiality (interpreted to privacy in a modern version (Nova, 2001b)). Setting out, and abiding by these principles gives grounds for a relation-

ship whereby the patient can feel secure and trust that their interests are taken into account, and that they are not going to suffer harm. Establishing and maintaining this relationship is vital in the medical context where the patient seeks to improve their health and is absolutely reliant on the doctor to achieve their goal. Doctors, for their part, are equally reliant in purely pragmatic terms (if not for humanitarian reasons) on helping them to achieve that goal. What is the impact, then, of online consultations on this relationship?

We begin the discussion by looking at the impact on trust (as a precondition for health care) of an online relationship, and follow with an assessment on the prevention of harm and injustice and confidentiality. Finally, we consider the aspect of acting in the patient's best interests, and whether online consultations can provide the reassurance that the patient needs.

## Trust

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The question of "duty of care" raised in the previous section, whilst expressed in legal terms, captures some sense of the secure and trusting relationship we are arguing is the foundation of a healthcare relationship. The lack of physical presence and its impact on trust has been taken up by Bauer (2004) who argues that the empathy and sense of connected-ness built through trust and understanding, encourages healing. A key point of his argument is that trust is built in the doctor-patient relationship through a certain amount of risk-taking, particularly on behalf of the patient. In the case of online health care he claims that "cybermedicine makes risk-free interactions easier and more commonplace" thus reducing the opportunity for building trust. His conclusion, founded on arguments from moral philosophy, is that as the pursuit of healing is the fundamental ethical principle of medicine, the diminishing of the healing practice is immoral and that "cybermedicine encourages morally inappropriate physician-patient relationships."

If we accept this argument, we should ask: What risks are there in the healthcare relationship, and are they reduced in the "diagnosis at a distance" setting? The patient is putting their health and intimate information in another person's hands and thus implicitly accepts some risk, whether in terms of correct advice and treatment, or confidentiality. The doctor's risk is in the reliability of the information received, knowledge of the patient's history and circumstances, and reliability of the prescribed course of action. These issues of validity, reliability of information, confidentiality and the impact on them of remote consultations are discussed in the following paragraphs.

## **Prevention of Harm and Injustice**

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The questionnaire approach used in online consultations as a means of ascertaining medical needs, typified in our early example, illustrates the degree to which the “empathetic” doctor-patient relationship has been stretched. Even if we were to discount Bauer’s argument regarding interconnectedness, and return to the more generally accepted principles of the Hippocratic Oath—which by its existence attests to the recognition of the power imbalance between professional (expert) and layperson—it is hard to see how the questionnaire approach to medical consultations can adequately address the prevention of harm, and the imbalance between expert and non-expert, which could result in injustice. The dialogue between doctor and patient that is traditionally conducted face-to-face is an important aspect of a doctor’s practice especially with regard to his duty to prevent harm (as far as is reasonably possible). In practical terms, it is within the face-to-face context that doctor makes an assessment of the condition presented at that time, based on a number of factors that give an overall picture of the health of the patient—such things as skin tone and texture, condition of eyes, tongue, reaction to touch, emotional state, and many others. Thus, a rich picture of the patient is built based on the doctor’s experience (and tacit knowledge). In respect of the risk factor, which Bauer argues contributes to the trusting relationship, the validity of information received from the patient is more easily assessed, and for the patient it is more likely that their doctor’s credentials are professionally accepted. So under these circumstances it seems that risks are reduced.

Doctors in this familiar setting are also in a position to share information with the patient, and are in a much better position to establish that the patient understands what they are saying—whether it be information about the condition, or, vitally, information concerning drug use. Thus some measure of informed consent (an underlying principle of an ethical action) can be achieved. Whether informed consent is usual when patients are receiving prescriptions for drugs may be debated (as opposed to surgery where signed consent is explicitly required) but consent is certainly implicit in accepting the prescription. However, when completing an online questionnaire, the level of language competence and understanding within the medical context (discussed later) has serious implications for this generally held principle of informed consent—how informed is the consumer under such circumstances? This aspect is pursued later under the heading of “social perspective.”

## **Confidentiality**

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We questioned earlier the legal status of patient confidentiality, and raise it again as an ethical issue. Doctors who prescribe drugs online could argue that the precautions they take to ensure confidentiality are at least as good as the measures used in more

traditional settings. We cannot say that patient files are secure from unauthorised access in either the off-line or online environment (and some could argue that as patient records are transferred to electronic storage there is little difference). However, it would be safe to say that there is an increased opportunity to gain access to confidential material online, with much less risk of being caught, even where the best security measures are in place. If security measures are not in place, then patient confidentiality is not provided for. What is more, if access to this information is inadequately protected online, the extent of the spread of this information is potentially on a “massive” scale. Once leaked it would be impossible to contain, or conduct any damage limitation. Whilst the vulnerability of personal data is a general concern in online activities, and not exclusive to online medical practices, personal medical information is highly sensitive and warrants special care (under EU data protection legislation). We would argue that because this information is valuable to third parties (pharmaceutical and insurance companies, for instance) it is especially at risk online.

In some cases doctors and others are required to pass information to health authorities for the purposes of building data banks of public health information providing sets of statistics, which can be used to inform government policies regarding public health initiatives. Cooper and Collman (2005) note that “to operate effectively physicians need complete and accurate information about the patient” and are therefore in a position to provide detailed information for such statistic-gathering. Although this information in its statistical form is anonymous (that is, having no identifier to any patient) the amount of information collected, and the use of data-mining techniques can isolate and identify to a surprising extent. The authors point to studies by Sweeney (1997) who demonstrated that birth date alone can uniquely identify names and addresses of individuals from a voting list (12% success rate), when combined with birth date and gender the results increased to 29%. Additional information increases the chance of identification, with a full postal code and birth date bringing the identification rate up to 97%. We can see that just because the data has been anonymised confidentiality and protection of medical information is not assured for the individuals concerned.

Aside from the (legitimate) passing on of medical information by doctors, health data can be gleaned from the Internet activities of the patient/customer (Cooper et al., 2005). The authors refer to instances where IP addresses (the unique address of the computer accessing the Internet) “have been linked with publicly available hospital data that correlates to DNA sequences for disease.” Of course, anyone using the Internet can be routinely tracked to find out the sites they have visited in order to build profiles of Web users, but the linking to medical data is taking this a step further and into more serious waters.

## Patients' Best Interests

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We began this section with reference to the Hippocratic Oath. In a modern version the following has been added:

*I will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug.* (Nova, 2001b)

In part the sentence quoted underpins the notions of empathy expressed earlier, and its importance in the healing process. In doing so it is recognised that surgery or drugs may not be the best way forward. It could be argued that the practice of prescribing drugs online favours the assumption that drugs are the best solution to the problem. There is already a questionable cultural trend in the U.S. and the UK to use drugs as the first line of attack for many conditions. Patients visit their doctor and expect a solution to their condition in the form of pill, and it is often easier for doctors under pressure to prescribe drugs than investigate other possible causes (such as living conditions or life style for example). McCoy (2005) refers to this trend as the “over-biomedicalisation of healthcare” that is, the lack of attention to life context, and the reduction of illness to something that can be solved by prescription. This trend, according to McCoy, is as a result of pressure exerted by pharmaceutical companies, directly and indirectly through advertising (McCoy, 2005). The question that arises is whether, in the case of online medical consultations, the advising doctor would recommend against the use of prescribed drugs and offer instead “warmth, sympathy, and understanding?” Reducing the relationship to the completion of a questionnaire and the provision of a prescription drug supports Bauer's argument that “cybermedicine makes risk-free interactions easier and more commonplace” thus diminishing the healing relationship. This type of approach resembles more of a commercial transaction than a mutual effort to promote wellbeing, and if this is all that is needed why not have questionnaires at Pharmacy counters in towns, and bypass the doctor? The issue of questionnaires and the wider implications of conducting online transactions in the healthcare sector are further explored below.

## The Social Perspective

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The two cases reported at the beginning of this chapter (i.e., concerning Drs Franklin and Shindore) raise a number of social issues. In general terms, buying prescription drugs remotely encourages a culture of independence from recognised institutional

practices and undermines the ethos of risk associated with such drugs. Drugs that are designated prescription-only are considered to carry risk under certain conditions—if they were not they would be available for anyone to buy. The issuing of a prescription implies that an expert has taken the medical, and possibly emotional, characteristics of the patient into account, the risks, and benefits of prescribing the drug, and has recommended a course of treatment based on those factors. This assessment has taken place traditionally face-to-face, and incorporates the visual clues and existing personal knowledge of the patient referred to in the section “prevention of harm and injustice” above. By offering an “easy” route to buying drugs, it could be argued that the practitioner prescribing online is complicit in undermining the best practice advice of recognised professional bodies.

There is also a wider social implication to bypassing the traditional route and using an e-commerce model, and this is the issue of patient protection. Both the issuer of the drug and the receiver are taking a risk that has hitherto been mitigated by the levels of protection provided by regulation, whether it be legislation or professional codes of conduct. For example, The Royal Pharmaceutical Society of Great Britain (RPSGB)—the professional body for pharmacists in the UK—in their draft version of a revised Code of Ethics (RPS, 2006) offers substantial guidance on the professional role when dispensing drugs. Some of the principles they list are: making the care of patients your first concern, act in the best interests of individual patients and the public, obtain consent for ... treatment, care, patient information, encourage patients to participate in decisions about their care. Some of these principles have been discussed in the previous section (patients’ best interest, confidentiality) others such as consent and participation in decisions are discussed below.

In the previous section we introduced the notion of informed consent, and suggested that doctors in a face-to-face diagnosis were in a better position to gain feedback on the patient’s understanding of the diagnosis and treatment, and could to some extent be reassured that the treatment was consensual. In this section we discuss the impact of the remote approach to diagnosis and treatment via online methods on the notion of “informed.” At the level of individual applications for online prescriptions, the online questionnaire takes no account of the level of literacy of the patient—either in terms of understanding the terminology used in the context of health, competence in the language used in the questionnaire, or specific cultural interpretations. Under Section 4 of the RPSGB Code of Ethics “Encourage patients to participate in decisions about their care” (RPS, 2006) it is stated “Listen to patients and their carers and endeavour to communicate effectively with them. Ensure that, whenever possible, reasonable steps are taken to meet the particular language and communication needs of the patient” (Item 4.2 RPS 2006). Clear communication is considered to be important in the delivery of medicines. They also instruct the pharmacist to “make sure that patients know how to use their medicines” (Item 1.5 RPS, 2006).

It is hard to see how an online questionnaire can fulfil these communication needs. When completing an online medical questionnaire, a respondent may not completely understand a question and may “guess” an answer, or may misinterpret a question and give an invalid answer. These issues are extremely relevant where drugs are bought and sold in a global market place, where language competence and understanding of medical terminology can vary. A lack of understanding of the medical context, and particularly familiar medical culture, could have drastic effects.

To illustrate our point, the following questions (below) are taken from an actual online consultation questionnaire at <https://meds4yourhealth.com>. Notice that some of the questions are expressed in medical terms, which are not immediately obvious to a non-medical person.

- Do you suffer from or currently have Cardiac or (ischemic) heart disease?
- Do you suffer from or currently have Transient ischemic attack(s) (TIA's)?
- Do you suffer from or currently have Diabetes?
- Do you suffer from or currently have Epilepsy?
- Do you suffer from or currently have Hypertension (exceeds either value of 80/120 mm Hg)?
- Do you use MAO-inhibitors like phenelzine or moclobemide?
- Do you use NSAID's (nonsteroidal anti-inflammatory drug - f.i. salicylates, diclofenac, naproxen)?

While terms such as “diabetes” and “epilepsy” may be familiar to many, we suggest that it is doubtful that someone would know whether they had a “transient ischemic attack” or whether they suffered from hypertension that “exceeds either value of 80/120 mm Hg.” Also medical terms such as “MAO-inhibitors” and “NSAID” are not commonly used amongst the general population. These terms may be familiar to the local, or national, community from which the Web site is generated—but it cannot be assumed that they would be understood by people outside of that community.

So what of informed consent? According to the Council for International Organizations of Medical Science (CIOMS) International Ethical Guidelines, informed consent is defined as: “Consent given by a competent individual who: Has received the necessary information, has adequately understood the information, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation” (CIOMS, 2002). These guidelines refer to the research environment, as do the following noted by Tavani (2006) in a discussion concerning genomics research and quoting Alpert (1998): (1) individuals must “know and understand the nature of the information being re-

leased,” and (2) consenting individuals must be made aware of the party or parties to whom the information about them can be released. These requirements, he notes, are similar in ethos to conditions laid out in the Office of Technology Assessment (OTA) Report “Protecting Privacy in Computerized Medical Information” (OTA, 1993) whereby patients must (1) have adequate disclosure of information about the data dissemination process, and (2) be able to fully comprehend what they are being told about the procedure or treatment. In a footnote he points out that the OTA also say the patient must be “competent” to consent.

Thus, important questions are Who is considered competent, and what competencies are required? Do competencies vary according to context? Does online communication require different competencies? And finally, how would anyone operating in an online context offering consultations and selling prescription drugs know whether their client was competent or not?

The patient/client/customer (depending on which relationship model one uses) places themselves at risk in this context from the point of view of fully understanding the situation and thereby not being fully informed. Patients also run the risk that a legitimate consulting physician may not be present to evaluate the online questionnaire. Further, use of general questionnaires may not provide the necessary information for the determination of a number of important issues such as whether a particular drug (FTC, 2001): (1) will work for an individual, (2) is safe to use, (3) is more appropriate than another treatment, (4) may cause adverse reactions if an individual is taking another medication, or (5) may be harmful due to an underlying medical condition such as an allergy.

The risk, however, is not just on the part of the patient. Even with the best of intentions, a doctor entering into an online consultation, and pharmacist conducting an online transaction, may not be in a position to fulfil their professional responsibilities. The procedures used for assessment are less able to offer reassurances than face-to-face transactions. For example, if online questionnaires are not completed truthfully then medications will be prescribed on false information. Another important aspect is the authenticity of the patient request —does this person really have the symptoms the drug will alleviate, are they buying for someone else, or buying to sell on to others? We should bear in mind that it is possible for a minor (under 18 years old) to buy drugs. In a 2003 briefing to the U.S. Congress, an investigator reported that his 9-year-old daughter successfully ordered a prescription weight-loss drug on the U.S. Drug Enforcement Administration (DEA) controlled substance list (Lueck, 2003). In addition, his 13-year-old son ordered and received Prozac, a drug on the United States Food and Drug Administration’s (FDA) Import Alert list (Lueck, 2003).

The responsibility of the medical practitioner does not end in the prescribing of a drug. Follow-up treatment may be required. In the case of Dr. Shindore, one of the reasons given for withdrawing his licence to practise was that no treatment plan was

established. One wonders whether some purchasers are choosing to get the drugs online because they prefer a one-off interaction, and whether they appreciate the potentially harmful implications of such a one-off deal. Even if advice is given as to the period of time the drug should be taken, when a reassessment is due or what contra-indications may appear, the purchaser may not (a) take any notice, or (b) not fully understand. Furthermore, the purchaser of online drugs may find it difficult to effectively communicate concerns, developments, or changes in symptoms either through the lack of established online procedures or even where a facility is available difficulties may be experienced since he/she cannot be physically assessed by a medical practitioner.

Concerning the extent of responsibility in the online environment, it is interesting that the following disclaimer is included in the questionnaire.

*I declare without any restriction:*

*(a) that I have read the terms and conditions and the disclaimer on this Website and agree with their content and applicability*

It should be noted that this is only the first of a total of four clauses. This approach is surely very different from the type of doctor/patient interaction that takes place in a surgery—patients in the traditional role are not asked to agree to any “disclaimer.”

## Future Trends

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As technological developments advance and are incorporated into commercial practices some of the issues noted in the previous sections may be alleviated. We have not so far discussed the use of Web cams for example in overcoming the issue of face-to-face consultations, direct measuring techniques for aiding diagnosis, or legitimate access to a shared database of patient records (overcoming the problem of patient history). These technologies are in existence, and are currently used in the medical domain between trusted parties.

In the sub-sections that follow, we look at the previous three examples of available technologies and assess how they may help in the online consultation context. In each case we show how the legal, ethical, and social difficulties previously highlighted might be addressed.

## Web Cam (Problem Addressed: Face to Face Consultations)

### *Legal*

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The U.S. Federation of State Medical Boards guidelines clearly state that “e-mail and other electronic communications and interactions between the physician and patient should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship.” (FSMB, 2002), It is rather doubtful therefore whether in the U.S. a Web cam can be used as a substitute for a face-to-face physical interaction between a physician and patient (who has not previously been physically examined). In the UK however, the GMC’s guidelines for online consultations (as outlined in detail earlier) appear to indicate that it is possible to use a Web cam (video) subject to certain conditions (see GMC, 2006, paragraphs 39 and 40).

Some criteria relevant to utilising a Web cam are:

- Establish a dialogue with the patient, using a questionnaire;
- Adequately assess the patient’s condition (which may include performing a physical examination of the patient as far as is practicable via video);
- Discuss alternative treatments;
- Assess any contra-indication effects;
- Have sufficient dialogue with the patient regarding treatment options;
- Inform the patient’s general practitioner.

### *Ethical*

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The ways by which some of the ethical issues might be addressed are listed following the headings used within the ethical perspective section.

- **Trust:** The visual clues could encourage a trusting relationship, and help the patient feel more engaged in the consultation process.
- **Prevention of harm and injustice:** The lack of visual clues for the doctor discussed under this heading would be addressed with this technology, for example assuring the doctor that the patient understands the treatment (e.g., dosage), and the language competence of the patient.

- **Confidentiality:** The issue of vulnerability of data over a public network (the security issue) is not addressed by using this technology. An additional ethical issue may in fact be raised here with regard to the storage of visual data. This may be appropriate and helpful as a record of care, but visual data adds to the issue of confidentiality and security of data. It also reduces anonymity (which could be seen as a beneficial outcome or a disadvantage).
- **Patients' best interests:** Using this technology may have a benefit in diminishing the sense of engaging in a purely commercial transaction (as described earlier), thus fostering a better relationship between the patient and consulting clinician.

### *Social*

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Under this heading, we noted how online consultations could give the impression that the patient is engaged in something akin to a commercial transaction, thus reducing the import of prescription drugs. Using a Web cam could have the effect of elevating the apparently "casual" transaction of buying drugs to a more formal setting and thus reinstating a sense of medical "best practice." In addition this type of visual interaction allows for a more meaningful interpretation of "informed" both on the part of the practitioner, and the patient (each receiving feedback from the visual clues). It should be noted of course that this only applies to non-visually impaired participants. However, it should also be noted that when using a Web cam the voice is normally transmitted at the same time and therefore for the visually impaired the traditional consulting room setting is fairly represented. An interaction using a Web-cam would address some of the communication concerns of the Royal Pharmaceutical Society of Great Britain (discussed under this section).

### **Diagnostic Measuring Techniques (Problem Addressed: Lack of Physical Contact and Capability to Make a Full Patient Assessment)**

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Technologies are being utilised to aid diagnosis and to transmit data to a central database, or General Practitioner. For example, trials are being conducted in the UK that use devices to monitor blood sugar levels as an aid in the management of diabetes and transmitting the patient data to a central location, such as a local general practitioner (Farmer et al., 2005).

## *Legal*

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Returning to the GMC guidelines the following are addressed by using diagnostic measuring techniques.

- Adequately assess the patient's condition;
- Assess any contra-indication effects;
- Perform a physical examination of the patient.

## *Ethical*

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- **Trust:** In some ways using a technology such as this may encourage trust in that the patient and the consultant have a clearer indication of the patient's condition. However, this depends to a large extent on the trust placed in the technology itself, which is playing a mediating role. While it could be said that any technology used in a consultation (i.e., in traditional face-to-face settings) also needs to be trusted, the presence of the doctor who can oversee the technology at first hand would arguably give some confidence to the patient, and the doctor, that all is working correctly.
- **Prevention of harm and injustice:** Using this type of technology helps to build a "rich picture" of the patient's condition and thus contributes to the prevention of harm.
- **Confidentiality:** As previously described, the vulnerability of transmitted and stored digital data constitutes a risk to confidentiality.
- **Patient's best interests:** As above, using a diagnostic device may alleviate the sense of a purely commercial transaction, fostering more of a relationship between the patient and consulting clinician.

## *Social*

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Making use of technology that is specific to the medical profession could have the effect of elevating the "casual" transaction of buying drugs into a more formal setting, thus reinstating a sense of the medical aspect and confirming social norms that are described as "best practice." It may also encourage the patient to participate in decisions about their care (in the case of the research with sugar levels and diabetes, which serves as the example for this section, the ethos is about encouraging patient "self-management" of their condition). As further information is provided this technology serves to further "inform" the patient, and also helps to address the issue of the "authenticity" of the patient.

## **Shared Patient Record Database (Problem Addressed: Adequate Medical History and Feedback)**

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### *Legal*

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The GMC (2006) suggest that practitioners should:

- Justify medicines/treatment proposed;
- Assess any contra-indication effects of medicines/treatments proposed;
- Keep a record of all medicines prescribed.

The U.S. FSMB (2002) asks for:

- Documented patient evaluation (including a patient history and physical evaluation).

A patient record would satisfy these requirements.

### *Ethical*

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- **Trust:** Where consultants have access to the patient's records—as on a shared database—it would be argued that the reliability of the information received and the knowledge of the patient's history and circumstances are improved. Such a situation is likely to improve the reliability of the prescribed course of action. However, the reliability of the information on a shared database cannot be assured—in which case there is a risk that the consultant assumes the correctness of the information (which may be an error) and the prescribed treatment is therefore not fitting. The outcome of this could have extremely serious consequences (perhaps fatal).
- **Prevention of harm and injustice:** Although using a database to access a patient's records contributes to the rich picture (providing increased relevant information about the patient) harm may not be prevented, as noted in the previous paragraph.
- **Confidentiality:** Issues of the security of the information are still an issue, particularly as the patient data is stored (i.e., available over a prolonged period of time), and accessible by many authorised personnel who also may alter and update the record (which can be a source of error).

- **Patients' best interests:** Providing a patient history and maintaining up-to-date accurate records would further the patient's best interests. This information also enables follow-up treatment, and a feedback mechanism.

### *Social*

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Access to the patient's records would eliminate the reliance on a questionnaire such as the one described earlier, where questions using medical terminology could cause confusion and misunderstanding. The consultant would be able to see at a glance the relevant and most recent medical situation of the patient. Thus in this respect there is a benefit. The records could also serve to provide an additional means of authenticating the patient (i.e., that this is the patient claimed, that they do have the condition they are claiming to have, and when they last had a prescription issued).

We can see from the previous examples, and reference to the earlier discussions and drawbacks of the remote consultation, that introducing new technologies (as described in the examples above) could alleviate some of the problems. As with the introduction of most technologies, other problems may be generated—such as the reliability of electronic patient records—but a trade-off is an inevitable part of the decision-making process.

## Summary and Conclusion

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In this chapter, we have provided an overview of the practice of online healthcare, highlighting some of the benefits and problems associated with this phenomenon. We focused on the use of online consultations to facilitate the sale of prescription drugs, and outlined the related regulatory frameworks, which exist in the United States and United Kingdom. Further, we discussed some legal, ethical, and social issues of concern, which may arise with regard to the use of online consultations.

Some legal issues of concern discussed were liability for patient care—medical malpractice (in light of the extent to which a duty of care in an online consultation is comparable to that which exists in the traditional doctor-patient relationship), negligence and contractual obligations, confidentiality of patient information, EU/UK data protection law regarding the security of medical data, and jurisdiction issues (related to the relative locations of an online doctor and a patient, and bringing a claim against an online doctor).

In our discussion of ethical issues, we questioned the reasons for buying online. One reason may be that someone may want large quantities of a particular drug—much easier to get online by visiting different sites. The purchaser may be contemplat-

ing suicide, or may be planning to sell the drugs on at a profit and bypassing any regulations that protect the user. Other issues were patient confidentiality; informed consent, and finally, the implicit assumption that prescribing drugs is the most appropriate form of treatment for the patient.

With regard to social issues, the subtle but clear move from a face-to-face interaction towards a simple “form-filling” exercise is likely to encourage a casual and less informed approach to drugs that carry some risk, and has an added impact in undermining the status of the medical profession. We are also concerned about the level of understanding on the part of the purchaser, the verification of authenticity of the patient request and the potential for a lack of continuous monitoring and advice concerning the patient’s medical condition. Finally we suggest that with online consultations, the risks to the consumer are greater and the level of protection less, compared to the traditional off-line medical consultation.

All of the present concerns previously discussed are relevant to future developments. Technology is moving on, and the Internet has brought with it an irrevocable cultural change. Opportunities have arisen that allow consumers more choice in how they purchase goods, and from whom. With developments in mobile technologies and increased access to the Internet, the preponderance and use of online pharmacies is likely to grow.

Many of the concerns we have raised will continue to be relevant. These include:

- **At the medical level:** Issues related to disassociation of remedy from cause, disassociation from personal expert advice and the consequent clinician/patient relationship that is formed over time (which includes knowledge of the patient’s personality, medical history, and social context).
- **At the purchaser level:** Language competence and understanding in multicultural states, and cross-national transactions.
- **At the technological level:** Issues of confidentiality and security of personal data.
- **At the legal level:** Liability for malpractice, negligence or contractual obligations, issues of confidentiality, data protection, and enforcement of inter-jurisdictional offences.

Advances in technology can impact on the provision of online healthcare, both in terms of providing solutions to present difficulties and in creating further legal, ethical, and social concerns. Technology can provide solutions by aiding doctors in making better diagnoses at a distance, for example: use of Web cameras for examining patients and use of medical instruments that can be used to carry out various medical tests on a patient (as we have previously discussed). Technology can also provide

better security for information, aid regulatory bodies, and enforcement authorities in their duties and help promote public awareness of important issues. Unfortunately technologies are also likely to be abused or subject to malfunction or failure. This further raises legal concerns such as where legal liability for failure of a technology lies, ethical concerns such as the potential for misuse of a new technology, and social concerns such as how a technology impacts on current norms and practices.

The previous discussions imply a need for continuing regulatory and ethical scrutiny of the evolving social phenomenon of online medical practice. Present regulatory frameworks and ethical codes of conduct may not adequately address the future scenarios that could develop. Although legitimate Internet pharmacies appear to adhere to the provisions of the existing regulatory frameworks, as discussed earlier, the problem really lies with rogue pharmacies that are driven by commercial profits and operate without regard to either regulatory or ethical guidance.

Having seen the rather futile efforts to dissuade Internet users from utilising its resources (for example, by the music industry to prevent the sharing of music files), we argue that the medical profession will need to consider how they can best adapt to Internet practices using technology, policy and legislation, and consumer education, to adequately protect the patient. Any adaptation, however, should not lower the established medical standards and hence put patients at potential risk. The global risk to the health and well-being of everyone dictate that ethical codes of conduct and regulatory frameworks need to be constantly reviewed and updated not only to address online medical practitioners, but also other players that facilitate this commercial activity. Thus appropriate ethical guidance and regulation should be aimed at technologists, delivery specialists, and credit card companies among others in the stream of online medical commerce. The need to protect consumers from the potential harmful consequences of online consultations should be a core principle, guiding the conduct of all commercial entities. We argue, finally, that perhaps the only way forward into the future is for more international consensus, cooperation, and agreement to establish global ethical and regulatory standards for online medical practice, to safeguard medical practitioners and recipients of medical advice and treatment.

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