Informing Irish Patients:
Implications for direct to consumer advertising of prescription medications

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ACKNOWLEDGEMENTS

This report is the result of several months of work by the members of the Patients’ Rights Research Team at Dublin City University. The Research Steering Group was convened in response to a tender for funding of this project by the Irish Patients’ Association under the leadership of Mr Stephen McMahon. This funding support came via a grant from the interim Health Information Quality Authority (iHIQA). The Research Team thanks iHIQA and the Irish Patients’ Association for the funding and support which made it possible for the three research assistants to work on the project. The researchers’ work laid the foundation for the initial draft of the Report.

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June 14, 2007

As this report goes to press, the Wellcome Trust has announced that they have identified genetic markers that indicate a predisposition to specific chronic illnesses such as bipolar disorder, diabetes and high blood pressure. Their work was completed in two years by 200 scientists analysing almost 10 billion pieces of genetic information involving highly complex calculations. This is the awesome power of technology which when used for good can be very beneficial to humanity.

Patients too, have enormous internal calculations to make when processing information about their illness, options and treatments. They must sift through facts and speculations, weighing the evidence for different options. That information must be both reliable and understandable. They must also go against those who would dam the flow of information and those who would open up a flood of information.

This DCU report maps out a framework of what needs to be done in order to respect patients’ rights to information and to be informed and promote good choices based on this. The research team built on their earlier report, Health Care Rights and Responsibilities, also conducted on behalf of the Irish Patients’ Association (O’Mathúna et al 2005). This called for an open and broad debate by all stakeholders on the implications of a constitutional right to equity of access to healthcare. During the recent election all parties agreed to facilitate such a debate during the term of the next government, with Fianna Fáil believing the most appropriate forum in which to address this is the all-party committee on the constitution. The report published here will make a valuable contribution regarding equity of access to information.

Finally, this report identifies a key role for that of information bearer. This role needs to be further defined and indeed regulated as it may cross many professional boundaries in healthcare.

I would like to thank Dr Dónal O’Mathúna, Dr Adam McAuley, Prof Anne Scott and the rest of the DCU team for their work in this area.

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EXECUTIVE SUMMARY

Health information is vital for an effective healthcare system. This report examines a number of issues surrounding the provision of information to Irish patients, with a focus on medication information. A number of barriers to information provision were identified. Health literacy is a significant factor in the use of patient information leaflets for medications. Patients should have access to accurate, understandable information.

A small pilot study was carried out where third level students read and commented on two patient information leaflets for medications. This study showed that these leaflets were written at a level requiring close to Leaving Certificate reading skills. All the third-level students who participated in the study understood the information. However, this raised questions regarding their readability by Irish people who do not have such high literacy levels.

Information on prescription medications in the form of direct to consumer advertising was examined. This is currently not permitted in Ireland or the European Union, but is in the United States and New Zealand. The arguments for and against this approach to providing information to patients were examined. The report concludes that the limitations outweigh the benefits of this approach. Rather than focusing on a right to information, the report prefers to recommend a right to be informed. This right implies that patients should be provided access to evidence-based, accurate, understandable information.

The legal context of the right to information in Ireland was examined under a number of headings. The legal right to information and medical intervention under Irish law is excellent in some very specialised areas of medical intervention such as clinical trials and mental health. This same right is inadequate and imperfect for general medical intervention. The right of patients to access their personal healthcare information under Irish law is very good. However, improvements are needed to facilitate access to personal healthcare information for purposes other than treating the patient. The right to information concerning healthcare professionals, services and products under Irish law is currently in transition and is moving in the right direction. However, caution is needed to ensure that any right to information about the quality of healthcare services is put in context.

There is a significant dearth of empirical data on many of the areas discussed in this report. Research is needed into the effectiveness of various strategies to inform patients. Only then will it become clear whether Irish patients are better informed and whether this is helping to improve their health.

RECOMMENDATIONS

A right to be informed, rather than a right to information, should be conferred on patients in Ireland through appropriate legislation.

Healthcare professionals should be encouraged and resourced to spend time informing patients about their health and treatment options and allow sufficient time for questions and discussion.

Patients should take seriously their responsibility to inform themselves about their health, their medications and any other treatments they might be receiving.

Pharmacies should seek to provide private areas for patients to discuss their medications with pharmacists.

Patient information leaflets for medications should be made available in a range of literacy levels and in different languages.

Patients should be encouraged to have their literacy level evaluated so that they will know which leaflets will be most informative for them.

“Talking labels” and other innovative ways of promoting patient understanding of medication information should be encouraged and developed.

Direct to consumer advertising of prescription medications, as practised in the United States and New Zealand, should not be permitted in Ireland or the European Union.

Empirical research should examine the impact of all forms of advertising and information provision for healthcare products and services.

Pharmaceutical companies should continue to play a role in informing patients about their products via healthcare professionals and via objective, understandable information given with the medications, such as currently occurs with patient information leaflets.

High-quality, evidence-based health information should be made available on the Internet through the European Union and/or the Department of Health and Children. Such information should be accompanied by clear warnings of the dangers of self-diagnosis and self-treatment by patients.

Patients should be made aware of the importance of evaluating health information on the Internet and instructed on how to evaluate health information.

Educational strategies should be developed that encourage and develop patients’ skills in evaluating health information.

Research should be undertaken to evaluate Irish patients’ accessibility to health information on the Internet.

The right to information in relation to medical intervention under Irish law should be made more uniform to make informed consent as clear as it currently is in clinical trials.

The right of patients to access their personal healthcare information under Irish law is to be commended.

There is a need for legislation to regulate access to and use of personal healthcare information for purposes other than treatment of the patient and at the same time protect patients’ privacy.

The right to information about healthcare professionals, services and products under Irish law should continue to be developed.
We live in an age of technology where people have ready access to more information than ever before. Information about almost anything, including healthcare, is at people’s fingertips via the Internet. But with access to all this information, are Irish patients better informed? How informative is the information?

Informed consent is held out as the bedrock of ethics in modern healthcare, with the presumption that patients ought to make their own healthcare decisions. But to make informed decisions, patients need information that does inform them.

Respecting the right to information is said to help patients become better informed. This report examines some of the types of information available to patients and considers whether or not this information helps patients make more informed choices. Health information is defined in the broadest sense as information related to health, illness, treatment and prevention of illness, health professionals and health services. Specific types of health information are examined in more depth, including patient information leaflets on medications, direct to consumer advertising of medications, and health information on the Internet. This report recommends the provision of health information that we believe could help Irish patients become better informed and thus enable people to give truly informed consent. We recommend that legal and practical steps be taken to increase the availability to the public of unbiased, evidence-based health care information.” (O’Mathúna et al 2005 p8).

Active Citizenship Network (2006), the authors and primary promoters of the European Charter of Patients’ Rights, report that the right to information is the most controversial of the proposed rights. That organisation is conducting a survey of all health-related European citizens’ organisations to examine perspectives on what this right means and how it might be implemented. The results of this survey were not available as of May 2007.

The use of “rights” language as a means of promoting patient goods has its limitations. The strengths and weaknesses of a rights-based approach were examined in depth previously and will not be re-analysed here (O’Mathúna et al 2005). The limitations of rights language include concerns that every right could become viewed “as an absolute entitlement” and could “reinforce individualistic leanings.” (ibid. pp7, 56-65). An absolute right to information weighs patients down with stacks of information. However, this information may or may not help patients make informed healthcare decisions. Another limitation with a rights-based approach is its tendency to neglect another important dimension of rights: the role of duties and responsibilities. If patients have a right to information, who is responsible to provide this information? And who has the responsibility to ensure that the information provided truly does further patient care?

This report focuses on the right to information for competent adults who are English speakers. Making information available to those with intellectual disability or diminished capacity to consent is another issue that requires in-depth and careful examination, which is beyond the remit of this report. So too for those who are not native English speakers.

1 INTRODUCTION

The European Charter of Patients’ Rights articulates among its fourteen proposed rights, the Right to Information (Active Citizen Network 2002). This right states, in part, that:

Every individual has the right to access all kind of information regarding his state of health, the health services and how to use them, and all that scientific research and technological innovation make available… The health services have the duty to make all information easily accessible, removing bureaucratic obstacles, educating health care providers, preparing and distributing informational materials… This information can come from either public or private sources, provided that it meets the criteria of accuracy, reliability and transparency.

This right is also directly connected to the right to consent and patient autonomy. In an earlier critical review of the European Charter of Patients’ Rights, the authors of this present report concluded that: “The Right to Information can be wholeheartedly recommended. We recommend that legal and practical steps be taken to increase the availability to the public of unbiased, evidence-based health care information.” (O’Mathúna et al 2005 p8).

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Information about medications is particularly important to patients. Pharmaceutical manufacturers generate and hold much of this information, putting them in an idea position to provide such information. Yet there is controversy over how pharmaceutical companies should provide this information. Patient information leaflets are widely available, but written at reading levels that may go beyond many patients’ literacy levels. Direct to consumer advertising (DTCA) is permitted in some jurisdictions, but its impact raises concerns among many. If patients have a right to access all kinds of information, do restrictions on DTCA interfere with that right? How should the provision of health information on the Internet be viewed? Should it be monitored and evaluated? If so, by who?

Does the Department of Health and Children have some responsibility to provide health information? Or should the role of the Department of Health and Children be to filter and regulate information? What is the role of the Health Service Executive (HSE)? When patients obtain health information, do they have responsibilities to evaluate and check this information? How should patients’ different intellectual and language capacities be taken into account in the provision of health information? These are questions this report seeks to address.

The report also examines the legal right to information concerning healthcare in Ireland. The law in Ireland has addressed information about medical interventions, in particular regarding informed consent for medical interventions. The patient’s right to information about his or her own medical record is found in Data Protection and Freedom of Information statutes. Such information is protected by principles of confidentiality, but can be accessed for reasons other than patient treatment. Patients may also have a right to certain information about healthcare professionals and healthcare services and products.
2 THE ROLE OF HEALTH INFORMATION

Patients who are informed about their health can take a more active role in managing their own healthcare. Research has shown that patients with active involvement in their care adhere better to treatment regimes and have higher levels of satisfaction (Hall, Porter and Katz 1998). Active involvement includes knowing the side effects, interactions and contraindications of medications. To ensure information informs patients, it must be appropriate to the patient’s level of education, culture, beliefs, attitudes and expectations (Doak, Doak and Root 1996, Dowse and Ehlers 2000). Written information must be at the proper literacy level. This chapter will focus on information about medications to exemplify the issues that must be addressed regarding any form of health information.

2.1 PROVIDING INFORMATION ABOUT MEDICATIONS

Health information can be given to patients in many different forms. Patients receive information verbally, from healthcare practitioners, supplemented with written and possibly recorded or audiovisual material. Patients may access information on the Internet, although it is unclear how recorded or audiovisual material. Patients may access information on the Internet, although it is unclear how recorded or audiovisual material. Patients may access information on the Internet, although it is unclear how recorded or audiovisual material. Patients may access information on the Internet, although it is unclear how recorded or audiovisual material. Patients may access information on the Internet, although it is unclear how recorded or audiovisual material. Patients may access information on the Internet, although it is unclear how recorded or audiovisual material. Patients may access information on the Internet, although it is unclear how recorded or audiovisual material. 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The large amount of information provided on side effects may cause fear and anxiety. Ninety percent of parents of children with Attention Deficit/Hyperactivity Disorder (ADHD) believed that concern about medications and confusing information prevent many children from accessing treatment for the condition (Richwood 2000). However, earlier research showed that warning patients about side effects did not result in less adherence and can actually enhance patient adherence to medication regimens (DiMatteo and DiNicola 1982).

Written health information has an important role to play in the delivery of healthcare and helps reinforce and educate patients (Koo, Koss and Aslani 2003). The benefits of written information include increased patient knowledge and understanding, leading to increased compliance. Leaflets play an important role in reinforcing the medication information discussed between patient and healthcare practitioner, much of which may be forgotten or recalled incorrectly by patients once they leave the consulting room.

2.3.1 Health literacy

Having identified the significance of written health information, it is important to recognise that effective communication between healthcare professional and patient happens only when health information is tailored to the patient’s literacy and comprehension levels.

A patient’s level of comprehension can vary, due to factors such as stress or fear of disease. Patients who normally have a good level of comprehension may find themselves unable to understand information relating to their own treatment due to stress. When stress levels rise, it is even more important to adults that material provided is not challenging to read (Doak, Doak and Root 1996). Health literacy has been defined as “the capacity to obtain, interpret and understand basic health information and services and the competence to use such information and services to enhance health” (Department of Health and Human Services 2000).

Levels of health literacy are problematic throughout the world. One study in the United States assessed people’s comprehension of fifty of the most common health words (Williams et al 2002). Among patients, 35 percent understood the word “orally”, 22 percent understood “nerve”, 18 percent understood “malignant” and 13 percent understood “terminal”.

The International Adult Literacy Survey (IALS) was a large scale comparative assessment of adult literacy (Morgan, Hickey and Kelloggah 1997). The survey was conducted in three rounds, in 1994, 1997 and 1998, with a total of 22 countries or regions taking part, including Ireland. Five literacy levels were identified:

- **Level 1**: Person with very low skills who may be unable to determine the correct amount of medicine to give a child from information printed on the pack.
- **Level 2**: Person who can only deal with very simple, clearly laid out material. People at this level can read but they have difficulty learning new skills.
- **Level 3**: Person has just minimum literacy requirements for coping with the everyday demands of a complex, advanced society.
- **Level 4**: Person has the literacy requirements to cope with a complex, advanced society.
- **Level 5**: Persons scoring the highest literacy levels.

The IALS survey found that 500,000 Irish adults had difficulties with everyday reading tasks, like reading the dose on a medication bottle (Morgan, Hickey and Kelloggah 1997). An Organisation for Economic Co-operation and Development survey (2004) found that 10 percent of 15-year-old Irish students were at Level 2 on the IALS scale. Many factors contribute to health illiteracy, including poor general reading ability, learning disorders like dyslexia and patients’ cultural background.

Health illiteracy has major implications for both patients and society. Patients who lack functional health literacy lack the ability to understand essential information about their condition (Williams et al 1998). One study found that patients who did not have adequate health literacy were twice as likely as other patients to be hospitalised during the study period (Baker et al 1998). Williams (2002) found that patients who score low in functional health literacy have difficulty reading and understanding health promotional material, hospital admission letters, appointment notices and medication instructions. Health illiteracy may lead to a continuation of unhealthy behaviours, inability to navigate the healthcare system, difficulties accessing appropriate care, waste of health resources and time, anxiety and fear, and poor compliance with treatment plans.

For patients with low functional health literacy, their ability to use medication information leaflets is greatly diminished, resulting in decreased adherence to therapy regimes and increased hospitalisations and healthcare costs (Baker et al 1998, Weiss and Palmer 2004).

Poor adherence to treatment plans is linked to increased mortality (Betas Blocker Heart Attack Trial 1982, Coronary Drug Project 1980). Knopper (2000) reported that patients with low literacy are 5 times more likely to misinterpret a prescription. Other reasons for patients not taking their medications as prescribed include difficulties with reading instructions, calculating doses or remembering to take medication. Patients rarely admit they are functionally illiterate (Winslow 2001) and may excuse to hide this due to fear and embarrassment (Smith 2003). Easier to read health information would greatly assist users of the healthcare system and reduce occasions when they may be embarrassed by their difficulty in understanding the information.

2.3.2 Focus on written information relating to medications

Some of the most complex and yet important health information available to patients comes in the form of medication information leaflets. These can range from one-page leaflets to more elaborate brochures. They were initially provided for a number of reasons:

- to respond to consumer demand for medication information (Livingston, Hayes and Ladenheim 1996);
- to assist patients who forget the information they receive verbally (Wilson et al 1992, Ascione and Shimp 1984);
- to inform patients more fully in the belief this would increase patient satisfaction (Johnson, Sandor and Tyrrell 2003);
- to overcome the limited provision of verbal information by pharmacists and other healthcare professionals (Morrow, Hargie and Woodman 1993, Livingston, Hayes and Ladenheim 1993).

Written information is intended to instruct patients how and when to use a medication, and to promote an understanding of the purpose, advantages and dangers of the prescribed or advised medication (Gustafsson et al 2005). The patient information leaflet is the method most widely used to convey health information (Kenny et al 1998) and reinforces the information given orally to the patient (Buck 1998). Patient information leaflets in each medication package should provide the information necessary for patients to take their medication safely. This assumes that patients are familiar with the words used and their meaning. As noted earlier, health literacy may be a problem for some.

While much has been presented on patients’ right to information, rights entail responsibilities. Patients also have a responsibility to expend some time and effort comprehending the information they are provided with. This would apply irrespective of who provides the information or how (Rheingold 1985 p136). Research indicates that patients may be failing to honour this responsibility. The 2004 Irish survey found that less than half (47 percent) the patients, in general, always read the information leaflet included with their prescription medication, one third (33 percent) said they sometimes read the leaflet and 14 percent said they never read it (Irish Patients’ Association 2004a). When asked about their last prescription, 63 percent said they had read the leaflet and 21 percent said they had not (Ibid.). Raynor and Knapp (2000) reported that 20 percent of patients did not notice package inserts and only 60 percent of those who had seen them, read part or all of the text.

For information to benefit patients, they must read, understand and act upon the information. The Irish survey did find encouraging results regarding the readability of information leaflets. The information evaluated was found to be very easy to understand by 38 percent of patients, fairly easy by 42 percent, fairly difficult by 6 percent and very difficult by 3 percent (Irish Patients Association 2004a). Among those who do not generally read the leaflets, 10 percent viewed them as fairly difficult to understand and another 12 percent claimed they were very difficult to understand.

In addition to information on how to take their medications, leaflets describe when to take them and can include information on determining the correct dose. Patients will be given information on how to monitor themselves for beneficial and adverse effects, and be told what to do if they miss a dose or take too much (Gazmararian et al 2003). Some have deemed the most useful information on these leaflets to be that related to indications, potential adverse events, dosage and administration (Amery and Van Winkel 1995, Berry et al 1997). All this requires active engagement of the patient with the information if it is to have the desired benefits.

With such vital information available on these leaflets, a number of reasons are given to explain why numerous patients do not read them:

- Some claim that leaflets are too dull and perceived to be lacking in authority (Kenny et al 1998, Coulter 1998).
- The US Surgeon General, Richard Carmona, states that prescription medication labels “read more like legal disclaimers than useful or actionable health information” (cited in Food and Drug Administration 2006b).
- The leaflets are limited in size, use small type and are printed on both sides of often very thin paper, resulting in a document which is difficult to read. This problem is magnified for patients whose vision is impaired. Pharmacy studies have shown that the visual acuity needed to read the average label on over-the-counter medication is 20/50 at 165 inches with 20/20 vision needed to read labels on some brands (Scott 2004).
- Low functional health literacy.
2.4 PILOT STUDY OF INFORMATION LEAFLET READABILITY

Given the importance of the information on these leaflets, this research team undertook a pilot study of the readability of a small sample of information leaflets. This pilot study was conducted to explore the feasibility of evaluating the usefulness of prescription information leaflets. The objectives of the study were twofold: firstly, to calculate the readability level of two patient information leaflets using validated formulae; and secondly, to assess third-level students’ comprehension of these leaflets using validated tools.

2.4.1 Study part 1

The study used three readability assessment tools that are commonly used to assess written healthcare information (Meade and Byrd 1989). These were the Flesch–Kincaid Formula (Flesch 1974), the ‘SMOG’ Formula (McLaughlin 1969) and the Fog Index (Gunning 1952). Details of their use are found in Appendix I. The three tools give a reading grade level based on the US education system. The SMOG formula also gives an estimate of the assessed person’s reading age. These readability formulae are not without drawbacks. They fail to consider patients’ personal interest in the material or their background circumstances and can overestimate the difficulty of a passage (Kitchin 1990, Mayberry and Mayberry 1996, Kenny et al 1998). Variations in readability estimates have been reported when different formulae are used (Kras, Svarstad and Bultman 2002). Other factors impact the readability of the text and are not taken into account in readability formulae, such as size of type, line length, the number of words per page, sentence structure and the use of white space. Patient information leaflets which require the patient to calculate the dose they should take are also likely to prove more difficult to comprehend. Nonetheless, such formulae are used widely.

Patient information leaflets for Difene Suppositories and Phenergan Oral Solution were randomly selected for assessment from several supplied by a community pharmacy. Difene Suppositories are a prescription only, pain killing medication used to reduce inflammation and swelling. They can be used following surgery or for conditions such as arthritis. Phenergan Oral Solution can be purchased over the counter and is used to treat allergic conditions such as hay fever or to prevent travel sickness.

2.4.2 Study part 2

The second part of the study assessed third-level students’ comprehension of the two selected patient information leaflets. The study was anonymous and no personal information was collected from the participants. The Cloze Technique was used to assess health literacy (Taylor 1953). Further details are found in Appendix I.

A section from each patient information leaflet was extracted and used as a Cloze test passage. Eleven students enrolled in undergraduate programmes participated in the study. Nine were from a health focused discipline and two were from non-health focused disciplines.

2.4.3 Results

2.4.3.1 Results of the readability formulae

<table>
<thead>
<tr>
<th>Formula</th>
<th>Flesch–Kincaid</th>
<th>FOG</th>
<th>SMOG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade</td>
<td>Index</td>
<td>Reading Age</td>
<td>Grade</td>
</tr>
<tr>
<td>Difene</td>
<td>10</td>
<td>12.49</td>
<td>16.22</td>
</tr>
<tr>
<td>Phenergan</td>
<td>7.8</td>
<td>10.89</td>
<td>15.85</td>
</tr>
</tbody>
</table>

The reading level predicted by readability tests is usually based on 50 percent comprehension of the information. A reader at that level would only understand 50 percent of the information. To understand the Difene information leaflet, someone would need to have a grade 10 or 11 reading level (according to the US education system) or have undergone 12-13 years of education (from the FOG index). In an Irish context, this corresponds roughly to someone having a Leaving Certificate level of education. The SMOG reading age was calculated at a little over 16 years.

For the Phenergan leaflet, the Flesch–Kincaid Formula gives a somewhat lower grade level than the other formulae. Overall, the results indicated that a slightly younger reading age would be needed to comprehend this leaflet, though still at post-Junior Certificate level.

2.4.3.2 Results of the Cloze tests

<table>
<thead>
<tr>
<th>Medication</th>
<th>Average Score</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difene</td>
<td>79</td>
<td>61</td>
<td>90</td>
</tr>
<tr>
<td>Phenergan</td>
<td>84</td>
<td>70</td>
<td>90</td>
</tr>
</tbody>
</table>

The average score from the Difene Suppositories leaflet was 79 percent, indicating that the material was understood by the third-level students who participated. The average score from the Phenergan leaflet was 84 percent, indicating that this material was also understood. The minimum and maximum scores for individual students are also given in the table.

2.4.4 Pilot study discussion

The pilot nature of this study must be emphasised. A very small number of participants were enrolled. The study demonstrated that patient information leaflets and health literacy could be assessed in an objective fashion.

The results of the readability formulae indicate that the patient information leaflets which accompany Difene Suppositories and Phenergan Oral Solution can be understood by students at an Irish third-level institution. However, the readability level at which they are written would be inaccessible to many Irish people judging by the low levels of literacy documented in a large international survey (Morgan, Hickey and Kellyagh 1997). The results from the readability formulae indicate levels for individuals for whom English is their first language and who understand written as well as verbal English. They do not take into account the difficulties encountered by individuals whose first language is not English, who have impaired vision, who have conditions such as dyslexia or those with intellectual disability. In modern Irish society it is conceivable that these patient information leaflets would be more difficult for patients to use than is indicated by the results of the readability formulae.

The findings of this pilot study are also limited by the involvement of mostly students from health-related disciplines. They would be expected to be more aware of and understand the terminology used in the leaflets, thus finding the material easier to comprehend. The lowest score in the Cloze test for each leaflet was obtained by a student from a non-health related discipline. If a larger study confirms that third level students enrolled in non-health discipline are at the borderline of understanding written medication information, these leaflets would clearly be expecting a lot from the general public.

2.5 USER FRIENDLY INITIATIVES FOR MEDICATION INFORMATION

Medication information needs to be made accessible to all in our society. This can be achieved in a number of ways. Greater attention should be given to the importance of facilitating discussions between patients and healthcare professionals about their medications. This could be achieved by allocating more time to discuss medications during doctor-patient consultations; by ensuring more healthcare professionals are trained to discuss medications, as is occurring through granting prescribing privileges to some nurses; and by provisions for greater privacy in pharmacies. Another approach is training in communication skills which the HSE is putting in place for all staff who have contact with anyone using HSE services (Hunter 2007).

Written medication information should continue to be available for patients, but must be formulated to make it accessible to all. Language must be simplified to eliminate medical jargon. The European Medicines Agency (EMA) has recently begun initiatives to make medication information more patient friendly. The Agency currently publishes European Public Assessment Reports (EPARs) for centrally authorised medicinal products. It has undertaken to provide EPAR summaries that will be easier for the general public to understand. They will be shorter, non-technical versions of the full EPARs and provide information related to how the medication works, indications for use, benefits and risks and the reasons why the medication received a positive recommendation for authorisation from the EMA. The summaries will initially be published only for newly authorised medications but will, over time, be published for all centrally authorised products on the market (European Medicines Agency 2006).

Beyond the actual words, other changes are needed to make patient information leaflets more patient-friendly and to encourage patients to read them. The leaflets may need to be rewritten to take into consideration which information is essential for patients to take the medication safely and effectively. Since people may be allergic to specific items in medications, they should be able to quickly identify all the ingredients, both the active medications and the non-medicinal ingredients.

Sentences should be shortened. The leaflets should include adequate amounts of white space, and highlighting could be used to identify different sections. Large print versions should be available for those whose vision is poor. Providing written medication information in a number of languages will also become a necessity for patients whose command of English does not permit complete comprehension of English leaflets.

Illustrations and pictograms have been shown to enhance the comprehension and recall of information (Dowse and Ehlers 2003).

Some general measures can be taken to promote more user-friendly health and medication information. Information must also be tailored towards an individual patient’s level of comprehension. A range of materials, written at different comprehension levels, could be developed. This would entail assessing each patient’s Functional Health Literacy as they present to a clinic to ensure that the information provided to them is appropriate for their level of comprehension. The methods used in our study show that such assessments can be done quickly and easily, at little or no cost. This could put to good use some of the time people spend waiting in various healthcare settings.

Patient input in preparing future information leaflets is important. The material should be tested and evaluated by patients before being put into widespread use (Dickinson, Raynor and Duman 2001, Kras, Svarstad and Bultman 2002).
In the United States, ‘talking labels’ have been developed. Several versions of these work on the basis of either the pharmacist or an automated voice recording the administration regimen for the patient. The patient can later listen to the instructions at home whenever needed. Talking labels are a valuable tool for patients who are visually impaired, dyslexic, forgetful or have literacy difficulties. They provide a strong sense of independence for patients, who otherwise would need help with their medications, or may even need to be cared for in a nursing home or assisted living facility. The main barrier to the widespread use of this new technology is financial, but with increased use, this may become less of an issue.

Innovation and creativity should be encouraged in the provision of patient-friendly information.

### 2.6 Health Information on the Internet

The Internet is another source of written health information that has created a host of new problems. While legal regulation can influence information available for products in one jurisdiction, “Regulators can find it difficult to deal with promotional material from another country, where the relevant legislation is different to that in their country or where promotional claims have no traceable or verifiable source, as can arise with advertising on the internet” (Collier and Iheanacho 2002 p1408).

The use of the Internet may demonstrate how much patients want more information about their health and potential treatments (Bandow 2003). Health information is pervasive on the Internet. At present, there are at least 100,000 websites giving health information. Health information will be accessed increasingly by the public. Almost 100 million US adults have sought healthcare information online and 75 percent of those accessing the Internet use it to find health information (Ager 2002 p31).

One of the major issues is evaluating this information. Some websites are provided by government agencies but a large number are commercial. Some provide unbiased, evidence-based information, but others appear to be designed only to sell their products. The Internet is also being used to sell counterfeit drugs, which is a different, though related, problem of huge magnitude around the globe (O’Mathúna and McAuley 2006).

Many government bodies and professional organisations claim that the way to respond to Internet health information is to provide guidelines to evaluate the information on websites. Among these bodies are the Food and Drug Administration (FDA), the American Medical Association (AMA), the World Health Organization (WHO), the Medical Library of America and the European Commission. These and other bodies have drawn up guidelines for health websites. Most of the recommendations are in agreement. A study done by the researchers in the US found that “many authors agree on key criteria for evaluating health-related websites, and that efforts to develop consensus criteria may be helpful” (Kim et al 1999 p649).

The following is a list of the common criteria used to evaluate health-related websites, taken from those compiled by the organisations identified above.

1. **Sponsorship:** Can you easily identify the sponsor? Sponsorship is important as it can help identify the site as respected or not. (Medical Library Association 2002)

2. **Currency:** Is the site updated frequently? (ibid.)

3. **Factual Information:** The site should be based on factual information as opposed to just opinion. This information should be capable of being verified from a primary information source, such as professional literature. (ibid.)

4. **Audience:** The site should say whether it is intended for professionals or the public. (ibid.)

5. **Transparency and honesty:** The name of the provider, the purpose of the website and all sources of funding should be clearly visible. (European Commission 2002)

6. **Privacy and Data Protection:** The policy for the processing of personal data should be clearly stated and be in accordance with the European Community Data Protection legislation. (ibid.)

7. **Authority of health related content providers:** The categories of content providers for each item should be clearly identifiable. (ibid.)

8. **The purpose of the website:** It should be transparent whether the purpose of the website is to inform, sell, raise money or something else. (Food and Drug Administration 2005)

9. **Feedback:** How does the website manage interactions with visitors? There should always be a way to contact the website owner with problems, feedback and questions. (ibid.)

10. **Quality:** Health information should be accurate, easy to understand and up to date. (Internet Healthcare Coalition 2000)

11. **Responsible Partnering:** Providers should make reasonable efforts to ensure that sponsors, partners and other affiliates abide by applicable laws and hold the same ethical standards as the sites themselves. (ibid.)

12. **External Links:** Critical to the quality of an Internet site are the links that connect people with other information. This information can be part of the same website, or a connection to a completely different website. The person or group responsible for link selection should have the expertise and credentials to evaluate critically the appropriateness of these links. (Health Summit Working Group 1999 p5)

The above is a representative list of criteria, and is not exhaustive. These criteria are not imposed on website providers, but are offered as guidelines. Professional organisations like the AMA could impose sanctions on their members, but commercial providers are not subject to sanctions. To enable patients to be in a position to judge the quality of the information on the Internet, some methods of monitoring websites have been put in place. The two most prominent approaches are self-applied quality labels or third party accreditation.

The best-known quality label comes from the Health on the Net Foundation, a non-profit Swiss organisation which has drawn up a list of guidelines very similar to those mentioned above. Sites which comply with these guidelines are authorised to display the HON label. More than 3,000 sites currently use this label. The most prominent example of third party accreditation is medCERTAIN. This is a pilot project of the European Union with several levels of accreditation, “the highest being medical assessment of the content and a rating by health care professionals” (European Commission 2002). It is also hoped that the medCERTAIN accreditation rating will educate users about the importance of evaluating health information on the Internet (Eysenbach et al 2001 p794).

Not everyone is positive about the way these criteria are being implemented. A 2002 study identified 98 different rating instruments. “Many were no longer functioning. Of 51 newly-identified systems, only 5 provided some information by which they could be evaluated” (Gaglardi and Jadad 2002 p571). This places the burden of evaluating the evaluations on the patient, who may not be the person best qualified to do this.

Another evaluation of these rating instruments concluded that “no organisation has the capacity to identify objectively what is good or bad information. Quality remains an inherently subjective assessment, which depends on the type of information needed, the type of information searched for and the particular qualities and prejudices of the consumer” (Wilson 2002 p600). Wilson determined that the medCERTAIN or HON mark was the best system at that time.

The Pew Internet and American Life Project examined the attitudes of patients towards health information websites. Among the reasons given by Internet users for rejecting a health information site, “Only 30% rejected it if it lacked endorsement of a trusted, independent organisation, and just 42% turned away from it if they could not determine the source of the information” (Fox and Rainie 2002 p17). This raises concerns for those endeavouring to promote public use of these quality ratings.

Another study, carried out on behalf of the WHO, evaluated various Internet codes and rating mechanisms (Risk 2001). This study concluded that most systems place a significant burden on the consumer. In the case of medCERTAIN, this is the burden of “being aware of the quality labels, and being able to interpret them” (Risk 2001 p6). The HON system similarly requires the patient to verify the claims of the information providers. With codes of conduct, other problems arise. “In the absence of real enforcement citizens are required to be interested, knowledgeable and caring, with the desire and commitment to apply critical appraisal of sites claiming to be in compliance of a particular code” (ibid. pp15-16). The Pew study cited above, and others, have found that the public is often not willing to carry out the critical evaluation that most professionals deem necessary.

Much remains to be done to combat Internet laissez faire. Governments and health information providers are a long way from ensuring that patients have access to unbiased, evidence-based health information, which, some would argue, they have a right to be able to access.
3 DIRECT TO CONSUMER ADVERTISING OF PRESCRIPTION MEDICATIONS

Information about medications could be made available to patients in the form of direct to consumer advertising (DTCA). Such advertising is reported to provide patients with information that encourages them to engage actively with their healthcare professionals. Proponents claim that if patients do not read or comprehend medication information leaflets, if healthcare professionals do not have sufficient time or suitable facilities to discuss patients’ questions, and if the quality of Internet information is too unpredictable, then pharmaceutical companies should have a more active and direct role in providing patients with information about their products.

DTCA of prescription medications is prohibited in every Member State of the European Union. Only two States in the world permit DTCA: the United States (US) and New Zealand (NZ). DTCA is permitted in print, television, radio and electronic media, but must still comply with regulatory guidelines. The European Parliament has stated that “patients have a legitimate need for and right to information on medicinal products, including those on prescription” and has called for “guidance for provision of information by persons responsible for placing medicinal products on the market” (Directive 2004/27/EC).

Pharmaceutical companies are ideally placed to provide information on medicines because they design, test, manufacture and monitor them. Like any other commercial legal entity, a pharmaceutical manufacturer has a commercial right to provide product information. However, medications are not like the majority of other consumer products. Medications are necessary to ameliorate a patient’s condition and health or even save a patient’s life. Taking a medication involves a balancing of potential benefits and potential risks. Healthcare professionals do not have sufficient time or suitable facilities to discuss patients’ questions, and if the quality of Internet information is too unpredictable, then pharmaceutical companies should have a more active and direct role in providing patients with information about their products.

Pharmaceutical companies must strike a careful balance between improving patients’ health and well-being, on the one hand, and making a profit to remain viable on the other. They invest in developing new products through research, but much of this investment yields little or no return. When research produces a medication that makes it to market, pharmaceutical companies are under pressure to obtain a good return from their investments. Concerns have been expressed that this pressure could result in pharmaceutical companies exaggerating the benefits of their products and minimising their potential side-effects. Government regulation is seen as an important counterbalance against the pressure to maximise profits. The State has a legitimate interest in preventing the pharmaceutical companies from acting in ways that may endanger the health of patients. Governments also have a responsibility to ensure that the medications paid for by the State are effective, safe and needed by those taking them. Careful deliberation is therefore needed before DTCA would be permitted in Europe and Ireland.

The need to regulate direct communication by pharmaceutical manufacturers to patients is accepted. Everyone agrees, no matter which position they take on this issue, that “DTCA advertisements are clearly influential” (Editorial 2005). However, two-thirds of the world’s States do not have laws regulating the promotion of medications or do not enforce the ones they have (Mintzes 1998). Regulation of direct communication by pharmaceutical manufacturers to patients involves balancing a number of competing interests. These will be discussed in the following sections.

3.1 INFORMATION PROVISION AND ADVERTISING

Central to this debate is whether DTCA provides informational content (informs) or provides motivational content (persuades). Information is knowledge derived from study, experience, or instruction. It could be argued that regulation of medication information should be permissive as information, being by its nature objective, should not pose a risk to patients. However, patients can be placed at risk by the omission of information just as they can by the provision of certain information. Information can be accurate and yet still misleading if it creates inappropriate expectations. Advertising emphasises the qualities of a product in order to arouse a desire to buy that product or patronise a service. It could be argued that the regulation of advertisements should be restrictive or prohibitive because of the dangers of promoting products that pose risks to public health if missed. The difficulty lies in drawing the practical distinction between information and advertising.

If we take a simplified example, clinical trials may involve administering medication X to a group of patients suffering from an illness and administering medication Y to another group suffering from the same illness. Such a trial may demonstrate that medication X is more effective in treating that illness. This fact is knowledge and is objective. Would the communication of this fact by the pharmaceutical manufacturer of X transform this communication of knowledge into an advertisement? Unfortunately, little or no discussion has occurred regarding the provision of information as opposed to advertising, or about distinguishing between information and advertising. The sole focus has been on DTCA.

3.2 ARGUMENTS AGAINST DTCA

3.2.1 Inaccurate presentation of risks and benefits

The primary argument against DTCA of prescription medications is that the purpose of advertising is unsuitable for disseminating medication information to patients and the public. Since advertising seeks to stimulate demand and create brand loyalty, it is natural for the pharmaceutical manufacturer to present products in the most positive light possible. Inaccuracies carry significant risks to the health and life of patients. US Congressman Henry Waxman sees the educational and informative possibilities of DTCA, but adds that the benefits will be realised “only if consumers are given clear and accurate information” (2004 p236). Empirical studies have raised serious questions about whether this occurs.

A study conducted by researchers at Harvard Medical School found that 80 percent of doctors consulted held that information in DTCA “was not presented in a balanced manner” (Weissoam et al. 2004 p219), resulting in a situation where “patients were more informed but not better informed” (ibid. p231). Medications are “presented in an unrealistically positive light” (Editorial 2005). An analysis of 67 advertisements found that only 13 percent used data to support their claims of benefit, with 87 percent using vague, qualitative terms. The researchers concluded that “these advertisements rarely quantify a medicine’s expected benefit, and instead, make an emotional appeal. This strategy probably leaves many readers with the perception that the drug’s benefit is large and that everyone who uses the drug will enjoy the benefit” (Woloshin et al. 2001 p1145).

DTCA often focuses on newly approved medications. However, little is known about the long-term risks of taking these medications (Johnson 2002). Vioxx was the most heavily advertised prescription medication in 2000 at a cost of $161 million. Between 1999 and 2000, sales increased from $330 million to $1.5 billion (Klaiber, Barchard and Henke 2005). 84 million people took the drug between 1999 and 2004 before it was withdrawn from the market. It has been suggested that rapid increases in sales are needed for manufacturers to obtain returns on their investments in research and development (Mintzes and Lexchin 2005). DTCA may improve sales, but in doing so may put patients at higher risk of side-effects. Regulation of DTCA requires the inclusion of the main risks and possible side effects of the medication in question. However, a survey of primary care physicians in Colorado found that “advertisements fail to provide adequate information on cost, adverse effects, or alternative treatment options” (Robinson et al 2004 p431). There are complaints about “poorly defined risk profiles” (Lenzer 2002). In the table of regulatory letters sent to pharmaceutical companies by the FDA in 2001, out of thirteen complaints, five were for inadequate information, five were for minimising the risks and three were for overstating the efficacy (General Accounting Office 2002 p20).

3.2.2 Regulations are frequently violated

During the first two years of DTCA in the US, 33 products were fully advertised on radio and television. Of these, 17 (just over half) were found to have violated FDA guidelines (Lexchin and Mintzes 2002). The most common violations were inadequate communication of risks, overstatement of benefits and a lack of fair balance between presentation of risks and benefits (ibid.). Another study has shown that one-third of the direct to consumer advertisements in New Zealand have been found to be in violation of national laws (Medawar 2002). Violations are often repeated. The advertisements for one well-known product were found to have violated FDA regulation 11 times between 1997 and 2001, and another product by a different company to have incurred 14 violations (Lexchin and Mintzes 2002). An FDA
presentation to the Drug Information Association in 2000 noted an increase in advertisements of questionable quality and asked whether “outrageous overstatements of efficacy [had] become the norm” (Ostrove, cited in Lexchin and Mintzes 2002 p196). Some US legislators argue that the FDA is not doing enough to enforce current regulations and that false or misleading advertisements are not withdrawn quickly enough (Waxman 2004).

3.2.3 Educational impact

Studies have raised questions about the educational benefits of DTCA. A survey by the American Pharmaceutical Association found that 50 percent of respondents believed advertisements were not only educational in how the government (they are not); 43 percent believed that only “completely safe” medications could be advertised to the public (also untrue); and “there was a highly significant correlation between a positive attitude about DTCA advertising and false confidence in how DTC advertising is regulated” (Bedgrat et al 2001 p199). A study of DTCA in 18 US magazines over ten years found that most advertisements did not contain the basic information someone would need to judge the usefulness of a treatment (Lexchin and Mintzes 2002). Information on how the medication worked was not given in 64 percent of the advertisements; the likelihood of its success was not given in 91 percent; and 71 percent made no mention of alternative treatments. Few advertisements provided any information on the treated condition beyond its name or one symptom.

3.2.4 Inappropriate use of medications

Some raise concerns that DTCA can itself pose a health risk. For example, “DTC advertising can generate tremendous early demand for a newly approved medication, which may expose large numbers of patients to as-yet unrecognised side effects” (Berger et al 2001 p200). The Vioxx example was already mentioned. An extensive review by an independent French organisation found that between 1980 and 2000, 81 percent of all new approved medications offered little or no additional value over previously available products (Mintzes and Lexchin 2005). Three percent offered an important advance and 0.3 percent obtained the highest category of major advance.

Another concern relates to the choice of medications that become the focus of DTCA. One analysis found that in 1998, among the top ten medications in terms of DTCA expenditure, there were for seasonal allergies, one for male baldness and one for erectile dysfunction, leaving the reviewers to questions whether DTCA is an important public health tool (Berger et al p199).

DTCA may transform the professional relationship of doctor/patient to one of prescriber/consumer. According to the New Zealand Ministry of Health (2003), doctors in the US claim that patients pressurise them to prescribe medications that have appeared in an advertisement. Doctors also claim that disingenuous advertisements may lead to unreasonable patient expectations about the efficacy of a medication, and that patients may demand medications unsuitable for their needs. This could then lead to over-prescribing or inappropriate prescribing.

This issue is particularly problematic with depression, where patients read a list of symptoms, become concerned and consult a physician. A study used actors trained to behave like patients with symptoms of adjustment disorder (Kravitz et al 2005). This is a temporary reaction to stress, for which antidepressants are not a proven treatment and usually not prescribed. The patient-actors visited actual doctors and if they mentioned the antidepressant Paxil, by name, more than half received a prescription for the medication, if they did not ask for a prescription, one in ten were offered one by the doctors. The authors concluded that patient requests have “a profound effect” on prescribing patterns and that DTCA has effects that compete with evidence-based prescribing, thus potentially promoting overuse of medications. Such effects are widespread with conditions like depression (Lacasse and Leo 2005).

Such findings would appear to bolster the opinion of those who see DTCA as medicaising normal human experience. Such medicalisation has been described as “a process by which non-medical problems become defined and treated as medical disorders” (Kawachi and Conrad, cited in Mintzes 2002a p908). Among general practitioners in New Zealand (NZ), 74 percent believed that DTCA of “lifestyle” medications facilitates the medicalisation of a population that is healthy (Ministry of Health 2003 p20). “Lifestyle” medications attempt to treat “conditions” that fall between medical and social definitions of health, such as male pattern baldness. For example, traumatic events may lead people to get worried or anxious, but that does not necessarily mean that a medication is the best recourse. A period of rest and the help of good friends may be sufficient. DTCA may increase the medicalisation of human experience and the pursuit of medications to remedy all unpleasantness.

3.2.5 Cost factors

The cost of DTCA is another concern. Expenditure on DTCA for prescription medications has increased exponentially in the US from $55 million in 1991 to $2.5 billion in 2000 (Mintzes 2002b). By comparison, $405 million was spent in Europe in 2003 on over-the-counter pharmaceutical advertising (Kalber, Borchardt and Henke 2005). In the US, the 50 medications promoted most by DTCA represented 95 percent of total prescription costs in 2000 (Lexchin and Mintzes 2002). The same 50 medications were responsible for almost half of the $20 billion increase in retail prescription medication spending during the previous year. Other reports have noted that around 40 percent of the money spent each year on DTCA is used on only ten medications, which are typically costly ones (Mintzes 2002b p13). This suggests to opponents of DTCA that heavy advertising of these medications is disproportionately increasing healthcare costs. This cost will be passed on to patients (either immediately by higher prices for medications, or later through higher insurance premiums or taxes). The claim is that this money could be better spent on pharmaceutical research and development.

Commentators note that in the debate surrounding DTCA what is lacking is “empirical evidence of its impact on patients’ health and health care” (Weissman et al 2004 p220). This makes it difficult to determine that patterns and changes are caused by DTCA. However, two empirical studies have been published in this area (Manisfeld et al 2005). One study contrasted the prescribing patterns in two US cities for sumatriptan, a medication used for migraines. In one city no DTCA was used and in the other a television ad aired recommending that people ask their doctors about a “surprisingly effective” new treatment for migraine. Much higher prescribing was found in the city exposed to the DTCA. The second study found that after a medication was advertised on Dutch television without naming it, physicians were increasingly asked about it, prescriptions for it increased and its competitor decreased. From the small amount of research reported to date, DTCA changes to consultations and prescribing practice.

3.3 ARGUMENTS FAVOURING DTCA

3.3.1 Provision of information

The primary argument made in favour of DTCA is that it provides patients with information necessary to make decisions about their health (Bonaccorso and Sturchio 2002). A proponent states that “effective advertising of new drugs informs those with medical conditions about new drugs” and thereby motivates people to discuss the condition with their doctors (Kalten 2005).

3.3.2 Promoting patient autonomy

The primary argument made in favour of DTCA is that it provides patients with information necessary to make decisions about their health (Bonaccorso and Sturchio 2002). A proponent states that “effective advertising of new drugs informs those with medical conditions about new drugs” and thereby motivates people to discuss the condition with their doctors (Kalten 2005).
Informing Irish Patients

3.3.5 Educational value
Another argument is that patients give high approval ratings to DTCA and appear to retain information contained in them. One survey of over 1,800 people found that nearly 30 percent of those who had viewed DTCA acted upon the information provided (Kaiser Family Foundation 2001). Half of these viewers (50 percent) were prescribed a medication after approaching their doctor. While the majority of those who viewed the advertisements claimed they learned nothing from them, they provided more accurate responses to questions about the products than those who had not seen the advertisements. When asked how well they believe DTCA discloses information about a medication’s treatable condition or benefits, a large proportion of consumers rated the advertisements as “good or excellent.” Half the people believed that the advertisements were successful in communicating the potential side effects and dosage of the medication.

Supporters of DTCA believe that consumers are sophisticated enough to use DTCA to their own benefit. Over seven in ten (consumers) call it valuable and worthwhile. Nevertheless, only one in four considers DTCA to be objective and less than half consider it reliable. They have come to expect advertising to try and sell something. So, frankly, their resistance is up. At the same time, they have learned that DTCA can educate and inform them and they welcome this information even as they remain suspicious about the objectivity of its provider. (Food and Drug Administration 1995)

3.3.6 Impact of the Internet
Every State has a legitimate interest in protecting its population from harmful information and advertising. For example, States can decide that DTCA should be prohibited or controlled. The State can regulate the print, broadcast and electronic media located in the jurisdiction of that State to ensure that the media observe the DTCA regulation. However, a State cannot regulate print, broadcast and electronic media in the jurisdiction of another State. Therefore, a person resident in a State with a prohibition on DTCA can access websites in States that permit or have fewer restrictions on DTCA. It is as simple as changing the domain name address from “.ie” to “.com.”

However, research in 2004 showed that only 5 percent of Irish patients surveyed use the Internet to seek information on their medications (Irish Patients’ Association 2004a). This contrasts with other countries where various estimates have found that between 36 and 55 percent of those using the Internet are seeking medical information (Schmidt and Ernst 2004). Accessing health information was one of the most common reasons why 29 million people in the UK use the Internet (Melissios and Xu 2004). Given the apparent impossibility of controlling access to information on the Internet, DTCA is proposed as a method of providing people with objective and reliable information about medications and to encourage patients to talk to healthcare professionals about potential treatments.

3.4 LEGISLATIVE APPROACHES TO DTCA
States accord different weights or priorities to the factors listed above. The way States weigh and prioritise these issues determines whether a State’s regulation of DTCA is permissive, restrictive or prohibitive. The United States (US) and New Zealand (NZ) have legalised DTCA for prescription medications; the European Union continues to prohibit DTCA for prescription medications. The history of this legal regulation sheds further light on the benefits and risks of DTCA.

3.4.1 Permissive approach to DTCA: United States
In 1960, the US introduced the first federal law regulating aspects of the manufacture, distribution, sale and advertising of food and medicinal products, including medications: the Foods and Drugs Act 1906. Deficiencies were soon identified in this Act, to be expected since it represented the first foray into this area. For example, in US v. Johnson, 1911 the Supreme Court held that the 1906 Act prohibited false and misleading statements concerning the ingredients or identity of a medication. However, it did not prohibit a manufacturer making false therapeutic claims about the medication.

The US Congress removed this problem with the Sherrley Amendment Act 1912. This prohibited the labelling of medications with false therapeutic claims intended to defraud the purchaser. However, this amendment required the Government to prove that the manufacturer or supplier intended to defraud the public. A manufacturer or supplier could escape conviction by claiming that he or she believed in his or her product. Therefore, the marketing of medications that posed dangers to the public continued, including a worthless “cure” for diabetes, and a tonic containing radium that resulted in a slow and painful death (Swann 1998). These omissions were one of the motivating factors for replacing the 1906 Act with the Food, Drug and Cosmetic Act 1938, which forms the basis of current US federal law. Under the 1938 Act, the US Congress has permitted marketing and advertising of medications, including DTCA.

The 1938 Act has been amended a number of times. In 1962, the Kefauver-Harris amendments transferred regulatory authority for prescription medication advertising from the Federal Trade Commission (FTC), which exercises authority over general advertising, to the FDA. The FTC retains control of over-the-counter medication advertising. The US Congress did not specify who would be the audience for the material regulated by the FDA. Healthcare professionals, primarily doctors, were perceived as the only intended audience for such promotions (Novitch 1984 p307).

The 1962 amendments require that advertising include a brief summary of the side effects, contraindications and effectiveness of the medication being promoted. The purpose of this requirement is to assure that doctors, who have limited time to find and study medication information, have accurate and balanced medication promotional materials. This requirement is referred to as the “fair balance requirement”.

In 1970, the FDA responded to strong consumer interest in treatments prescribed or recommended by their doctors by requiring pharmaceutical manufacturers to include “patient package inserts” (PPIs). As noted in Chapter 2, these PPIs are written in intricate and scientific language and often are difficult for the average patient to comprehend. PPIs represented the first direct communication by pharmaceutical manufacturers to patients (Kendellen 1985 p174).

The First Amendment of the US Constitution guarantees the right to freedom of speech. In 1980, the US Supreme Court interpreted this to include commercial speech (Central Hudson Gas & Electric Corporation v Public Service Commission of New York, 1980). Soon after this decision, in the early 1980s, the first DTCA for prescription medications appeared. The FDA cannot require pharmaceutical manufacturers to submit the content of DTCA for approval prior to release for two reasons. Firstly, this would interfere with the pharmaceutical manufacturers’ constitutional right to freedom of commercial speech. Secondly, federal law expressly prohibits requiring prior approval for advertisement. The FDA can offer guidance on DTCA and enforce compliance post-violation (Fisher 1985 p195).

Early DTCA was primarily in print. In 1983, the FDA obtained a voluntary moratorium on DTCA. This move followed the recall of Eli Lilly’s anti-arthritic medication benoxaprofen (Orrafex or Opren) by the FDA after only 5 months on the market due to severe adverse effects, including deaths. Prior to the recall, the company had launched an aggressive public relations campaign aimed at the public and health professionals, which resulted in prescriptions for the medication rising from 2,000 to 55,000 a week earning the manufacturer more than US$1 million a week in sales (Mintzes 2002b p12). The moratorium on DTCA was lifted in 1985 following research showing that consumers wanted further information about prescription medications and favoured DTCA. The FDA declared that the food and medication law restrictions that applied to physician advertisements also applied to consumer advertisements.

Pharmaceutical manufacturers started to use television and radio for DTCA during the mid 1990s. In 1997, amendments were made to the federal law in an attempt to protect consumers. Manufacturers who market prescription medications to consumers with advertisements that mention the medication’s use and/or effectiveness must include:

- the medication’s established name;
- the brand name (if any);
- the ingredients; and,
- a brief summary of information about side effects, contraindications, and effectiveness.

This form of disclosure is referred to as the “brief summary”. The FDA issued regulations and guidelines to ensure that pharmaceutical manufacturers comply with the law. If an advertisement is in print, it must also provide the medication’s specific risks in more detail. If an advertisement is broadcast by television, radio, or over the telephone, it must include the brief summary unless the advertisement contains a package that provides “adequate provision for the dissemination of the approved package labelling.” Adequate provision allows a consumer to acquire essential precautionary information while allowing the pharmaceutical company to “market” the product (Folitz 1999 p205).

Where an advertisement satisfies the adequate provision requirement, the brief summary can be reduced to a “major statement.” This statement discloses the product’s major risks in an audio and visual element of the advertisement. From this developed the rectifying of a list of potential adverse effects which is now common in DTCA. This reduction in what a pharmaceutical manufacturer must disclose in the advertisement facilitated wide-ranging DTCA (Pines 1999 p493).

In 1999, the FDA carried out a survey of patient attitudes to DTCA. About half of the patients indicated that an advertisement for a prescription medication had prompted them to seek more information. Of those who had seen a doctor in the previous three months, 27 percent indicated that an advertisement prompted them to ask a doctor about a suspected medical condition or illness about which they had previously not talked to a doctor (Pines 1999 p494).

In 1999 the FDA released the “Industry Guidance on Consumer Directed Broadcast Advertisements.” The function of this guide is to provide an approach to DTCA that permits advertising containing the medication’s purpose and effects...
while satisfying the statutory requirements and public policy goals. The FDA was “unaware of any data supporting the assertion that the public health . . . is being harmed, or is likely to be harmed, by the Agency’s actions in facilitating consumer-directed broadcast advertising” (Food and Drug Administration 1999).

The 1999 guide recommends that each of the following disclosures be made in broadcast product-claim advertisements:

- The advertisement should disclose a toll-free telephone number for customers to call and request that approved package labelling either be sent to them by mail or read over the phone to them;
- The advertisement should announce the availability of packaging information in a print advertisement available concurrently with the broadcast advertisement and appearing in a publication that reaches an audience similar in scope to that of the broadcast advertisement;
- Reference to an Internet address at which consumers may access the approved package labelling; and
- Disclosure that healthcare professionals may provide additional product information.

The FDA’s Division of Pharmaceutical Marketing, Advertising and Communications (DDMAC) is responsible for ensuring compliance with the 1999 guide. Where the DDMAC believes that a medication’s promotion violates the law, the DDMAC issues a “warning letter” to the pharmaceutical manufacturer that:

- informs the manufacturer that the promotional piece violates the federal law;
- provides the company with 15 days to respond; and
- if prompt and appropriate measures are not taken, the DDMAC promises further action without providing the manufacturer prior notification.

The DDMAC “warning letter” will also request that the manufacturer take specific action in order to bring the advertisement into compliance with the law. More than 100 such letters were sent in 1998 and over 90 in 2001. In 2005, over forty such letters were sent by the DDMAC (Food and Drug Administration 2006a).

The FDA has other methods of enforcement including powers of seizure, ability to seek injunctive relief, or criminal prosecution. To date, none of these more serious means have been invoked in relation to DTCA violations. Pharmaceutical manufacturers focus the majority of their promotional efforts toward healthcare professionals, spending nearly $23 billion dollars on promotion to doctors in 2003. However, promotional expenses for advertising prescription medications to consumers have continued to grow during recent years, exceeding $3.2 billion dollars in 2003 (IMS Health 2003).

There is no indication that DTCA will abate in the US. Indeed, vociferous critics of DTCA recognise that the constitutional protection of commercial speech prevents legal prohibition of DTCA. The role of the FDA in relation to DTCA is limited to ensuring that DTCA is informative, well balanced, and adheres to the 1999 guide (Palumbo and Mullins 2002 p41).

3.4.2 Permissive approach to DTCA: New Zealand

New Zealand (NZ) is the only other country that permits DTCA at present. The Medicines Act 1981 and Medicines Regulations 1984 currently regulate medication advertising in NZ, including DTCA. The NZ law prohibits any DTCA that is false or misleading. The following must be included in any DTCA:

- identity of the advertiser;
- quantities of the active ingredients;
- authorised uses;
- appropriate precautions to be taken in using the medication; or;
- contraindications, known or likely poisonous effects of, or adverse reactions to the medication.

Where a medication is a prescription medication, restricted medication, or pharmacy-only medication, this fact must be disclosed in the DTCA. This fact must be conspicuously displayed in printed advertisements or clearly spoken in an oral advertisement.

DTCA cannot claim any approval by the State or State agent. There are certain other restrictions on therapeutic claims in DTCA concerning specific diseases or conditions including arthritis, alcoholism, baldness, cancer, heart disease, and infertility. Any DTCA cannot claim that the medication:

- will prevent, alleviate, or cure/terminate the disease or condition;
- is a panacea or infallible;
- is or has been used or recommended by a healthcare professional or researcher;
- has beneficially affected the health of a particular person or class of persons, whether named or unnamed, and whether real or fictitious; or;
- invites correspondence or sending of hair, blood, urine, or other bodily specimen or photographs for the purposes of diagnosis or treatment.

Although NZ regulation of DTCA is permissive, NZ controls of DTCA are more stringent than those that exist under US federal law.

Doctors in NZ have expressed frustration at patients pressurising them to prescribe certain branded prescription-only medications. The doctors attributed this pressure to DTCA (Ministry of Health 2003 p.23). The professors of general practice in NZ’s Schools of Medicine and other researchers reviewed the local and overseas literature concerning DTCA in 2003. They concluded that little evidence supported a net benefit for the public health system from DTCA. On the contrary, the evidence suggested that DTCA harmed public health and was a serious menace to the fiscal sustainability of health systems (Ministry of Health 2003 p44). The key findings of the report were that DTCA:

- does not provide objective information on risks, benefits and options to assist patients to participate in healthcare decisions;
- has a negative effect upon the patient-healthcare professional relationship;
- compromises patient safety;
- promotes the medicalisation of normal health and ageing processes;
- has a negative effect on health funding which may create inequity in resource allocation; and,
- cannot be controlled by self-regulation or through central regulation.

The report found that patients needed better access to reliable independent information on prescription medications, health and treatment options. The report recommended that the NZ government establish an independent medicine and health information service to facilitate patients accessing information to assist them in making decisions about their treatment options.

The NZ Health Strategy (Ministry of Health 2000) and numerous other government strategies have recognised the importance of providing such information to patients. HealthEd and public health education campaigns provide general health information. Medsafe provides information specifically about medications. Healthline offers a telephone triage and help line. In 2004, the Ministry of Health commissioned research following the publication of its 2003 report (Ministry of Health 2003). The Ministry of Health's research examined patient attitudes to how information on medications should be provided. This research (Ministry of Health 2004) found that:

- Patients prefer information to be provided by healthcare professionals.
- Patients prefer verbal information accompanied by written information from the same source.
- Healthcare professionals and organisations such as the Cancer Society are considered the most reliable sources of information.
- Patients want information on side effects, cost, reliability and content of medications.

The report made a number of recommendations to improve health information being provided to patients (Ministry of Health 2004). These include:

- Provide communication skills training for healthcare professionals who communicate information to different demographic groups.
- Identify, develop and test written information to ensure it is of a good standard.
- Ensure there is concurrence between written and verbal information.
- Survey healthcare professionals to establish their views on information availability, quality and other matters.
- Conduct research on patients who are ill or in poor health and have restricted access to information.
- Encourage the evaluation of information provision to patients.
- Increase consumer education through educational institutions and mass media.

The Therapeutic Products Bill seeks to introduce more stringent regulation of DTCA. NZ’s health minister was reported to be planning to ban DTCA in 2005, but that has not materialised (Mansfield et al 2005). Any proposal to restrict DTCA may breach the freedom of commercial speech protected by the NZ Bill of Rights Act 1990. In 2006, a consultation document identified the issues raised by DTCA in NZ and internationally (Ministry of Health 2006). The results of this consultation will determine the legal status of DTCA in NZ. The outcome will depend on the weight attached to the freedom of commercial speech.
Any DTCA of an over-the-counter product must encourage the sensible use of the product, not be deceptive or exaggerated and must adhere to requirements concerning format and content. The 1993 Regulations permit disease awareness campaigns provided there is no direct or indirect reference to medications. Advertisements to healthcare professionals are permitted. The Medical Preparations (Advertising) (Amendment) Regulations 1996 made some minor amendments and permitted the advertising to the public of products authorised and intended for the treatment of Alopexia.

Directive 2001/83/EC on the Code on pharmaceutical products for human use repealed Directive 92/28/EC. However, Title VII of Directive 2001/83/EC retained the prohibition on DTCA for prescription medications. Ireland has not yet implemented this Directive, although it could be claimed that the 1993 Regulations comply with the 2001 prohibition on DTCA since it is more or less the same as that found in Directive 92/28/EC.

In July 2001, the European Commission proposed that the prohibition on direct communication between patients and the pharmaceutical manufacturer for medications to treat AIDS, asthma or diabetes should be relaxed for a five-year trial period. The Commission chose these three illnesses because patients suffering from these diseases require accurate, reliable and easily identifiable information. The proposal allowed for the “dissemination of information relating to certain medical products... in order to respond to the expectations of patients’ groups” (European Commission 2001). The proposal allowed patients to receive the information appended to the marketing authorisation and additional related information. The proposal required that information and its dissemination conform to principles of good practice. European or Member State authorities would have evaluated the information appended to the marketing authorisation. The European Medicines Agency (EMA) was to be notified by the pharmaceutical manufacturer of the additional related information. The EMA could accept or object to this information. However, if the EMA did not object within thirty days following notification of such information, the information would have been deemed to be acceptable. The EMA was responsible for coordinating the monitoring of the information on the medications by means of a database. The EMA was to provide an annual report on the application of the principles of good practice. The Commission proposal did not refer to allowing DTCA.

Groups representing healthcare professionals and patients opposed the proposal, including a group representing HIV/AIDS patients who had not been consulted about the proposal (Camp 2002 p33). Pharmaceutical manufacturers supported the proposal. In October 2002, the European Parliament rejected the Commission’s proposal by 494 votes to 42 (European Parliament Debates 2002). Members of the European Parliament (MEPs) opposed DTCA on the basis that it was detrimental to public health. MEPs were concerned that the Commission’s proposal was a precursor to the introduction of the permissive regulation of DTCA for prescription medications similar to that in the US. MEPs drew a distinction between advertising and information. MEPs required the information needed to make informed decisions. Many MEPs advocated the provision of accurate, objective, reliable and comprehensible information that had been validated by European regulatory authorities. MEPs raised concerns about Internet medication advertising and information. Three problems were identified. First, the nature of the Internet prevents the European Union from exercising control over advertising and information originating from outside the European Union. Second, information on the Internet was often inappropriate, unreliable and fragmented. Third, it discriminated against non-English speaking people because the majority of this information was in English.

Despite the defeat of this Commission proposal, in 2004 the European Parliament voted in favour of the Commission undertaking research on these issues and proposing a new Directive 2004/27/EC, which provides that the European Commission will undertake research on the practice of providing information to patients and the risks and benefits for patients. The Commission must consult with patient, consumer, doctor and pharmacist organisations, Member States and other interested parties. The Commission will compile a report following these consultations and present it to the European Parliament and Council within three years of the entry into force of the Directive. Following analysis of the data arising from its research and consultations, the Commission must, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non-promotional information on medications and other treatments. It must also address questions regarding the legal liability of those who provide this information.

3.4.4 International guidance

There is limited international guidance on DTCA of prescription medications. In 1988 the Member States at the World Health Assembly approved the World Health Organization’s Ethical Criteria for Medicinal Pharmaceutical Promotion. Promotion is defined as including “all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs” (World Health Organization 1988). This is the only international standard for medication promotion. It opposes DTCA for prescription medications and medications for certain serious illnesses requiring the intervention of healthcare professionals. The WHO holds that any State must be cautious in permitting DTCA where there is considerable potential for harm and little if any documented evidence of benefit. However, further research is needed to evaluate the extent of these potential harms and to define more precisely the nature of these harms. Although this guidance from WHO is not legally binding, it may form the basis of an international treaty in the future.

3.5 CONCLUSION

The vast majority of States seem unlikely to drop their opposition to DTCA. There are difficulties evaluating the benefits and detriments of DTCA, and little empirical evidence on the topic. Most research has focused on the attitudes of different interest groups towards DTCA. Currently, the DTCA debate takes the form of claim and counter claim.

However, States must realise that their ability to restrict or prohibit DTCA has been undermined by the Internet. One poll has shown that more than 98 million US adults have sought healthcare information online and 75 per cent of those accessing the Internet use it to find health related information (Ager 2002 p31). Whether a similar situation will develop in Ireland is unclear given that 5 percent of Irish adults have personal computers in 2004, down slightly from 37 percent in 2003 (Kennedy 2006). However, the Communications Minister Mr Noel Dempsey is promoting a rapid increase in Internet penetration through broadband connections.

States appear to have two options. On the one hand, they can maintain their opposition to DTCA. States could then offset the impact of DTCA by providing patients with accurate, objective, reliable and comprehensible medication information on the Internet and warn patients of the dangers of using other forms of Internet information. On the other hand, States could permit DTCA and provide patients with accurate, objective, reliable and comprehensible medication information on the Internet. Either way, States cannot ignore the prevalent and growing influence of the Internet on our interconnected world.
4 RIGHTS, AUTONOMY AND ADVERTISING

One of the central arguments used to support DTCA is that it respects patients’ autonomy and facilitates the exercise of people’s right to information. Restrictions on the provision of information are seen by some as a violation of individual rights. Such an approach is in keeping with the widely promoted claim that when ethical principles conflict, individual autonomy should trump all other ethical principles. In this view, those opposed to DTCA raise concerns of harm to patients. Individual autonomy acknowledges those concerns, but gives autonomy higher priority.

A general concern about a rights-based approach to healthcare is that it can promote excessive individualism and undermine relationships which are grounded on trust (O’Mathuna et al 2005 p8). When trust diminishes, concern for rights also diminishes (O’Neill 2002b). Critics of DTCA note its emphasis on individualism. A study examining how DTCA tries to persuade people to use the products reported that “individualistic appeals were found more often than collectivistic appeals” (Sumpradit, Ascione and Bagozzi 2004 pp151-152). Advertisements were given a score of 1 to 4 under various headings. Out of a possible 48 points, individualism scored 36 and collectivism, 8. For the authors of this study, individualism included an appeal to self-sufficiency, freedom of choice, autonomy and pleasure; collectivism appealed to such values as sharing, mutual reliance, collective goals and caring for others (ibid. p142).

Given the vulnerability of many patients, and the complexity of many issues surrounding decisions about prescription medications, many patients are not self-sufficient. Therefore, in the name of individual autonomy, harm could be suffered. Advertising has so saturated society that some argue that it continually deceives and coerces people. “It is impossible for a consumer to act autonomously, as our society is so overwhelmed by coercion that buying decisions are made without our being aware of the influences we have become accustomed to” (Tillotson 2002 p2).

Individual autonomy promoted by advocates of DTCA claims that “the principle of autonomy places the patient at the centre of decision making about his care” (Vendu and Castello 2006 p60). Pervasive individual autonomy allows one “to act on one’s own judgement without the interference of others” (Stratit and Gill 2005 p127). But the idea of non-interference can minimise the role of knowledgeable healthcare professionals and interfere with the common goal of promoting patient health.

The dominance of individual autonomy has been critiqued. Professor Onora O’Neill has claimed that, “The supposed triumph of individual autonomy over other principles in bioethics is, I conclude, an unsustainable illusion” (2002a p73). We are all influenced by others and we all depend on others, to one degree or another, to achieve our aims and desires. O’Neill proposes instead what she has called “principled autonomy.” When applied to DTCA, her ideas provide some helpful direction.

O’Neill’s critique of individual autonomy arises from an imbalance between rights and duties. In our earlier report we noted an important distinction between two categories of human rights: civil and political rights, and, economic and social rights (O’Mathuna et al 2005 p32). Civil and political rights are liberties and other people should not interfere with someone exercising that liberty. For example, the right to privacy protects personal and intimate aspects of that individual’s life and other people are prohibited from violating someone’s privacy. Economic and social rights are those that provide an individual with an entitlement. Someone has an obligation to satisfy this entitlement and is therefore a duty-bearer. However, “modern rights language focuses on reciprocity, rather than action, on rights rather than obligations” (O’Neill 1996 p127). If the right to health information is seen as a civil and political right, no one should interfere with the freedom of the consumer to seek out that information. But if the right to information is seen as an economic and social right, someone has a duty to provide the information. We have argued that the right to information should be seen as an economic and social right; this right places a duty on someone to provide the information.

Our earlier report noted that rights must be grounded in more fundamental principles if they are to be more than arbitrary proclamations (O’Mathuna et al 2005). Rights should be seen as entailing obligations. “Any human right must have as its counterpart some obligation: a right that nobody is required to respect is simply not a right” (O’Neill 2002a p78). If patients have a right to information, who has the duty to provide that information? With prescription medications, is it the pharmaceutical company? The prescriber? The dispensary? The government? All this raises another, even more fundamental questions: What information? All information about the medication? Or only certain types of information?

4.1 WHO SHOULD PROVIDE THE INFORMATION?

The first set of questions asks: Who is in the best position to provide patients with the information that will help them make informed decisions? Our view is that the pharmaceutical companies should not bear this duty. Such a duty would create an impossible conflict of interest for them. Patients are often in a vulnerable position because of their illness. Pharmaceutical companies are in positions of power and influence because they have the medications patients want and they often have many resources. Patients want to get better. Companies want to help them, but they also want to make a profit. To negotiate the conflict of interest, an intermediary is needed.

Such intermediaries would serve a couple of purposes. They should be able to recommend medications to patients without personally gaining from those recommendations. This points to the importance of prescribers remaining independent of undue pressure from pharmaceutical companies. Recent attention has been given to how gifts from pharmaceutical companies, once seen as unproblematic for prescribers, now raise ethical concerns because of their influence on prescribers and evidence-based prescribing (Sieries et al 2005). The ideal is that prescribers determine which medications a patient truly needs based only on the best evidence available.

A duty to inform patients means that healthcare professionals who prescribe must take on two roles. They should interpret patients’ signs, symptoms and desires; and they can discern as best as possible what patients truly need. Their training and experience in the personal, humane side of healthcare gives them the expertise to do this. They also need to interpret medication information to discern as best they can what medication (if any) will meet patients’ needs most effectively and safely. Their training and experience in evidence-based practice gives them the expertise to do this.

Because of the unequal power relationship between patients and the pharmaceutical industry, and its inherent conflict of interest, some distance should be put between the two. The responsibility to inform patients should lie with healthcare professionals. Since doctors are under time constraints to do this effectively, other healthcare professionals, after receiving necessary training, should be involved in informing patients about their medications.

4.2 WHAT TYPE OF INFORMATION?

The second set of questions addresses the type of information patients should receive to become better informed. The right to information is not a right floating in abstract philosophy. It is a right with a purpose. That purpose in a healthcare context is the good of patients’ health. The right to information is not about the provision of any and all information about a medication. It is the right to specific information that will help patients make the best possible decisions that will promote their health. Patient information leaflets that patients cannot understand could be viewed as satisfying patients’ right to information. Patients are getting information. But such leaflets do not satisfy a patient’s right to be informed. Such information does not help patients make better, informed decisions.

4.2.1 The right to be informed

For this reason, we suggest that this whole discussion would be better framed around the “right to be informed,” not the right to information. Little research has been conducted in this area, but what is available suggests that DTCA does not help patients make better decisions. It appears to draw patients and prescribers away from evidence-based decision-making.

An obligation to inform patients would mean that the information provided patients should be unbiased, evidence-based information. Techniques of manipulation or deception would be inappropriate. Yet many of the techniques used in all advertisements can be exploitative, targeting people’s vulnerabilities. Appeals are made to people’s fears or sense of identity. Rhetoric, not information, is more often found in advertisements. For example, the use of celebrities and opinion leaders may be more common than factual information.

The use of celebrities in DTCA has been criticized as not being educational. For example, ice-skater Dorothy Hamill appeared in DTCA in the US praising Vioxx and its impact on her arthritis pain. Viewers may then be motivated to obtain the medication...
because of the celebrity, not because it is the best thing for them. The best evidence may suggest something very different. For example, even before Vioxx was taken off the market, the American Rheumatology Association recommended that it and other NSAIDs “only be used as a last, not a first, resort, and then only with great care because of their side-effects” (Lenzer 2002). The appearance of patient advocacy groups in DTCA could similarly be viewed as inappropriate with objective information being ethically preferable.

4.2.2 Evidence-based information
If patients have the right to be informed, as opposed to simply the right to information, accuracy and objectivity of information is crucial. We have reservations about the wording in the European Charter of Patients’ Rights which proclaims “the right to access all kind of information” (Active Citizen Network 2002). Instead, our previous report recommended increased provision of “unbiased, evidence-based health care information” (O’Mathúna et al 2005 p8).

The small amount of empirical evidence available does not support claims that DTCA provides such information. Pharmaceutical advertising must be held to the highest standard because of the consequences of misinformation or misuse of information through misunderstanding. “When a medical product is advertised on the basis of misleading, incomplete or simply untrue technical information, when an over-the-counter ‘cold remedy’ is sold with the promise but without any hard evidence that it can relieve symptoms and prevent complications, when known and dangerous side-effects are hidden behind a generic ‘with this as with all medicines, check with your doctor’, then seemingly simple ‘truth in advertising’ becomes a moral imperative and ethical principles (if not the law) have been violated” (Solomon 1991 p362). We maintain that DTCA does not provide patients the type of information they need to make informed decisions about prescription medications.

4.2.3 Checking information
One of the problems with making decisions today is the amount of information available. How can we know which information to trust? We must have criteria upon which to judge the information available to us. This requires “active inquiry rather than blind acceptance” which requires that “we can trace specific bits of information and specific undertakings to particular sources on whose veracity and reliability we can run some checks” (O’Neill 2002b). To make informed decisions and avoid mistakes and deception, we must be able to check not only the information but also its sources. This is part of why professional writing places such an emphasis on referencing all sources accurately. Guidelines for evaluating health information on the Internet consistently make referencing of claims one criterion by which a website’s quality can be assessed. One example points to the importance of checking information. Articles about complementary and alternative medicine (CAM) sometimes claim that only fifteen percent of medical decisions can be supported by scientific research. This allegedly justifies the lack of evidence for some CAM decisions. If referenced, the 15 percent number is said to come from a 1978 report made to the US Congress. However, the comment in this report was based on a 1963 British survey of 19 physicians (White 1995). Checking demonstrates that the 15 percent claim is not based on current, reliable information.

Many patients might not have the time or resources to check all the information they receive. In some cases, healthcare professionals apparently do not check the information they base their decisions upon (O’Mathúna 2000). Recognition of a duty to inform patients would emphasise the importance of healthcare professionals checking literature to help inform patients. Patients who do not have access to the resources to do this should see healthcare professionals as vital resources in helping them check the healthcare information they encounter. Other patients may want to investigate matters further and check information themselves.

Healthcare professionals should be able to direct such patients towards high-quality, evidence-based information. The Internet contains such information, but before directing patients to such sources, their ability to access and negotiate the Internet must be evaluated and taken into consideration.

4.3 THE ROLE OF PHARMACEUTICAL COMPANIES
Pharmaceutical companies should still retain a role in helping inform patients, but not through DTCA. “To consumers, the corporation has the obligation to provide quality products and services. It has the obligation to make sure that these are safe, through research and through appropriate instructions and, where appropriate, warnings against possible misuse” (Solomon 1991 p361). The three-way interactions of pharmaceutical companies should make the best, evidence-based information available to healthcare professionals. Those professionals (doctors, nurses, pharmacists and others) should have a duty to inform themselves of the products patients discuss with them. They should have a duty to make the best, evidence-based information as understandable as possible for the patients they interact with. Pharmaceutical companies should also continue to make patient information leaflets available, in a range of literacy levels and languages. Patients must also accept a duty to inform themselves about the products they are taking and check the accuracy of all healthcare claims as best they can. Only when all involved accept their appropriate duties and responsibilities will the right to be informed lead to practical health benefits for patients.
5 THE LEGAL BASIS OF THE RIGHT TO INFORMATION RE MEDICAL INTERVENTION

We will examine how Irish law regulates the right to information in relation to medical interventions, then personal healthcare information, and, finally, information about healthcare professionals, healthcare services and products.

Medical interventions are defined as any form of diagnosis or treatment of a patient that interferes with that patient’s bodily integrity. The Irish legal system contains a number of different sources of law that regulate the right to information and medical intervention.

5.1 CONSTITUTION OF IRELAND 1937
The Constitution of Ireland is the most important legal source of Irish law concerning information and medical intervention.

5.1.1 Express constitutional right to information?
The Constitution contains express personal constitutional rights. However, there is no express personal constitutional right to information prior to medical intervention.

5.1.2 Implied constitutional right to information?
In addition to personal express constitutional rights, the High and Supreme Court have identified a number of implied constitutional rights. The High and Supreme Courts have identified an implied constitutional right to information in two situations. Firstly, in O'T v. B, 1998, the Supreme Court recognised that a child who was informally adopted has a right to know the identity of his or her natural mother. This right is clearly limited to the particular facts and circumstances of informal adoptions.

Thus, this freedom of expression and any implicit right to information does not apply where a patient is making a personal and private decision to accept or reject medical intervention.

The High and Supreme Courts have decided that information is essential to the exercise of two constitutional rights. These are:


It is suggested that the provision of such information cannot be categorised as an independent constitutional right. It is a subsidiary component or aspect when exercising the substantive constitutional right.

The following constitutional rights are relevant to medical intervention:

- The right to bodily integrity (Ryan v. Attorney General, 1965 and Re a Ward of Court (No 2), 1996)
- The right to privacy (Kennedy v. Ireland, 1987)
- The right to dignity (Re a Ward of Court (No 2), 1996)
- The principle of self-determination or autonomy (Re a Ward of Court (No 2), 1996)

A patient has a right to consent to or refuse medical intervention (Re a Ward of Court (No 2), 1996). A patient can only make an autonomous decision to consent or refuse medical intervention where he or she had been provided with information about the state of his or her health, the proposed medical intervention and the consequences of accepting or rejecting such intervention. Like the right to marry and the right of an unmarried mother to the custody of her child, it is suggested that a patient is entitled to information prior to exercising his or her constitutional right to consent to or refuse medical intervention. The treating healthcare professional is the person responsible for ensuring that the patient’s entitlement to information is satisfied. Confirmation of this entitlement to information will depend on a patient seeking a declaration before the High and/or Supreme Court. The considerable legal costs involved in doing this act as a significant deterrent to such legal proceedings.

5.2 STATUTE
There is no Irish statute that provides patients with a general right to information before deciding whether to consent to or refuse medical intervention. The European Convention on Human Rights Act 2003 may have general implications in terms of the right to information and medical intervention.

There are four statutes that guarantee a right to information to patients in one of three specific situations: patients participating in clinical trials, patients detained due to a mental disorder, patients undergoing genetic tests, and donors of human tissues and cells for another human being.

5.2.1 European Convention on Human Rights legislation
The European Convention on the Protection of Human Rights and Fundamental Freedoms (ECHR 1950) does not have any express right to bodily integrity or any express entitlement to information before consenting to or refusing medical intervention. This omission reflects the relatively primitive nature of human rights in the 1950s. The type and nature of human rights in contemporary international human rights instruments are more sophisticated. For example, the later Council of Europe Convention on Human Rights and Biomedicine 1997 and the Universal Declaration on Bioethics and Human Rights 2005 provide that a person may only consent to medical intervention where that person was provided with appropriate information as to the purpose and nature of the intervention.

The right to respect for private life in Article 8 of the ECHR is the right relevant to bodily integrity, medical intervention and consent. The European Court of Human Rights has adopted a broad interpretation of private life. This court held that Article 8 includes a right to personal autonomy (Pretty v. The United Kingdom, 2002 and Evans v. The United Kingdom, 2006), a right to physical integrity (K and Y v. The Netherlands, 1985, Botta v. Italy, 1998, Pretty v. The United Kingdom, 2002, YF v. Turkey, 2003 and Glass v. The United Kingdom, 2004) and a right to psychological integrity (Botta v. Italy, 1998, Pretty v. The United Kingdom, 2002, and YF v. Turkey, 2003). The European Convention on Human Rights Act 2003 requires the Irish Court to take account of decisions of the European Court of Human Rights.

The European Court of Human Rights has yet to rule on what information, if any, must be provided to a person before he or she decides to consent to or refuse medical intervention. The European Court of Human Rights has already noted the consent and information provisions of the Council of Europe Convention on Human Rights and Biomedicine 1997 and the Universal Declaration on Bioethics and Human Rights 2005 (Evans v. The United Kingdom, 2006). It is suggested that the European Court of Human Rights would decide that a person is entitled to information about the nature of medical intervention before consenting to or refusing intervention. Therefore, a person in Ireland could claim that his or her right to private life included an entitlement to information before consenting to or refusing medical intervention.

One significant potential shortcoming exists in someone’s ability to invoke the ECHR under the European Convention on Human Rights Act 2003. The 2003 Act provides that every “organ of the State” must perform its functions in a manner compatible with the State’s obligations under the ECHR. Therefore, the ECHR cannot be invoked before an Irish Court in relation to the conduct and activities of private individuals, including private healthcare professionals and providers.

5.2.2 Clinical trials legislation
There are two reasons why patients in a clinical trial have a right to information before consenting to participation in a clinical trial. Firstly, the primary purpose of a clinical trial is to establish the efficacy and safety of the trial medications. There is a possibility that patients will not benefit from the trial medications. Indeed, the health of patients may suffer from unpleasant, serious or even life-threatening side effects of the trial medication. Secondly, a clinical trial may involve the use of a placebo. A placebo is an inert substance given to a patient participating in a clinical trial instead of the trial medication. Recipients of a placebo obtain no pharmacological benefit by participating in the trial.
Clinical trials in Ireland are regulated by two pieces of legislation. The European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 seeks to implement European Union Directive 2001/20/EC on good clinical practice in the conduct of clinical trials on medicinal products for human use. This directive establishes minimum requirements and standards for clinical trials.

The Directive and the Statutory Instrument guarantee the right to information of potential participants in a clinical trial in two ways. Firstly, they establish what information must be provided to participants, how this information must be provided, and who is responsible for providing this information. They require that:

- A participant must have an interview with the healthcare professional responsible for conducting the trial or a member of the team conducting the trial, in which the participant is given the opportunity to understand the nature, objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.
- A participant must receive any information provided to the participant in the trial and informed consent involves a potential participant being informed of the nature, significance, implications and risks of the trial.
- A participant must be informed of his or her right to withdraw from the trial at any time.
- A participant must be provided with a contact point where he or she may obtain further information about the trial.

The Directive and Statutory Instrument place the responsibility of obtaining informed consent on the healthcare professional or professionals with responsibility for conducting the clinical trial.

Secondly, the Directive and the Statutory Instrument require approval from an Ethics Committee before commencing the clinical trial. The Directive and Statutory Instrument require an Ethics Committee to evaluate the adequacy and completeness of the written information to be given to participants and the procedures to be followed for the purpose of obtaining informed consent to participation in the trial.

The Control of Clinical Trials Acts 1987 and 1990 regulate those clinical trials not regulated by European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004. The Control of Clinical Trials Acts 1987 and 1990 adopt a similar approach to the right to information. Firstly, the person conducting the clinical trial must ensure that every potential participant is made aware of the following matters, before giving his or her consent to participation in the trial:

- The objectives of the trial;
- The manner in which the trial substance or preparation is to be administered;
- The risks and any discomfort involved in, and the possible side-effects of, the trial; and, Whether or not to be administered to some participants.

Secondly, Ethics Committee approval must be obtained before a clinical trial may commence. The Ethics Committee must have regard to the proposed procedures for providing potential participants with information.

5.2.3 Mental health legislation

The right to information is found in three areas of the Mental Health Act 2001.

Firstly, a doctor must examine a person before that person can be involuntarily detained. The 2001 Act provides that the doctor performing this examination must inform the person of the purpose of the examination unless, in the doctor’s view, the provision of such information might be prejudicial to that person’s mental health, well-being or emotional condition.

Secondly, where a patient is initially detained or the period of detention is extended, the patient is entitled to the following information:

- The provision of the 2001 Act under which the patient has been detained;
- The patient’s entitlement to legal representation;
- A general description of the proposed treatment to be administered during that patient’s detention;
- The patient’s entitlement to communicate with the Inspector of Mental Health Services;
- Confirmation that the patient’s detention will be reviewed by a Mental Health Tribunal;
- The patient’s entitlement to appeal to the Circuit Court against the Mental Health Tribunal; and,
- The ability for that patient to be admitted as a voluntary patient if the patient so wishes.

Thirdly, the 2001 Act establishes a rebuttable presumption that the consent of a patient involuntarily detained because of a mental disorder must be obtained where that patient is competent to consent. The 2001 Act provides that the consent of a bona fide patient will only apply where there was no express or implied consent or the patient’s consent was vitiated by fraud or deception. Trespass against the person applies where a patient consents to medical intervention and subsequently believes that the healthcare professional failed to provide the patient with relevant and necessary information before obtaining that patient’s consent.

In Walsh v. Family Planning Services Ltd., 1992 the Supreme Court held that a patient’s claim that the healthcare professional failed to provide relevant information before obtaining his or her consent will be decided by reference to the tort of negligence. The Supreme Court held that trespass against the person will only apply where there was no express or implied consent or the patient’s consent was vitiated by fraud or deception. Trespass against the person applies where a patient consents to medical intervention and subsequently believes that the healthcare professional failed to provide the patient with relevant and necessary information before obtaining that patient’s consent.

Clinicians may perform analytical tests on donated human tissues and cells before using these tissues and cells on other people. Such tests may provide important healthcare information for a donor. The 2006 Regulations require that a donor is informed of his or her right to receive the confirmed results of the analytical tests and have such results “clearly explained.” The 2006 Regulations contain similar requirements for donations by next of kin of deceased donors.

5.3 COMMON LAW

The common law comprises the legal principles articulated by judges adjudicating on disputes. There are two possible common law approaches to the provision of information before a patient decides whether to consent to or refuse medical intervention: the tort of trespass against the person and/or the tort of negligence.

5.3.1 Failure to obtain informed consent: trespass against the person or negligence?

Irish law requires that in general medical intervention should not occur without the patient’s consent. Trespass against the person is committed where medical intervention occurs without that patient’s consent. There are two exceptions to obtaining the patient’s consent prior to intervention: a patient with a contagious disease or an unconscious patient who requires emergency treatment (Re a Ward of Court (No 2), 1996). The issue is whether trespass against the person applies where a patient consents to medical intervention and subsequently believes that the healthcare professional failed to provide the patient with relevant and necessary information before obtaining that patient’s consent.

In Walsh v. Family Planning Services Ltd, 1992 the Supreme Court held that a patient’s claim that the healthcare professional failed to provide relevant information before obtaining his or her consent will be decided by reference to the tort of negligence. The Supreme Court held that trespass against the person will only apply where there was no express or implied consent or the patient’s consent was vitiated by fraud or deception. Trespass against the person applies where a patient consents to medical intervention and subsequently believes that the healthcare professional failed to provide the patient with relevant and necessary information before obtaining that patient’s consent.

The tort of negligence applies where the healthcare professional obtained consent bona fide and the patient claims that his or her consent was not informed because the healthcare professional failed to disclose risks associated with the intervention and possible alternative treatments.
5.3.2 Common law requirements for informed consent

The common law principles for informed consent were developed in a number of High and Supreme Court cases. These establish that: a healthcare professional owes a duty to inform the patient of any possible harmful consequence arising from the medical intervention, in order that the patient gives an informed consent to the intervention (Walsh v. Family Planning Services Ltd, 1992). The corollary of this duty of the healthcare professional is a common law right to be informed of any possible harmful consequences. The common law does not always develop in a smooth and consistent manner because of the nature of judicial decision-making. Therefore, there are aspects of this common law duty that remain uncertain. These are:

- **Adequate warning:** One aspect is what standard should be applied when deciding whether the warning given by a healthcare professional to a patient was adequate. There are two options. Firstly, there is the reasonable patient standard: what risks should be disclosed to a reasonable patient. Healthcare professionals must put themselves in the patient’s shoes when deciding what risks should be disclosed (Geoghegan v. Harris 2000). It has been suggested that this standard goes somewhat to ensuring that it is the patient who decides that the intervention should occur rather than the healthcare professionals. Secondly, there is the reasonable healthcare professional standard: what risks would be disclosed by a reasonable healthcare professional (Walsh v. Family Planning Services Ltd, 1992 and Bolton v. Blackrock Clinic, 1997). This standard allows the healthcare professional to determine what information should be provided to patients. It may be argued that the healthcare professional is best placed to determine what risks should be disclosed and what risks should not be disclosed. The prevalent standard in the Irish courts is that of the reasonable healthcare professional.

- **Treatment necessary to maintain the life or health of a patient:** The duty to inform the patient of any possible harmful consequences differs depending on whether the treatment is necessary to maintain the life or health of a patient. Where the procedure is necessary to maintain the life or health of a patient (non-elective), a healthcare professional may satisfy the duty to warn by having a limited discussion or warning of possible harmful side effects. Where the procedure is not necessary to maintain the life or health of a patient (elective), the healthcare professional will satisfy the duty by having a greater discussion or warning of possible harmful side effects (Walsh v. Family Planning Services Ltd, 1992). In Bolton v. Blackrock Clinic, 1997, the Supreme Court held that a healthcare professional satisfied the duty of obtaining a patient’s informed consent in relation to an elective operation by explaining to the patient the necessity for the operation, the nature of the operation and any possible harmful consequences that might arise from the operation. This distinction between elective and non-elective was maintained in Callaghan v. Gleeson and Lavelle, 2002. The difficulty with this approach and the right to information is that all medical intervention is elective in the sense that every patient has an absolute right to accept or reject the medical intervention. This elective/non-elective approach restricts the information for non-elective treatment and may undermine patient autonomy.

- **Causation and informed consent:** In a negligence action, a plaintiff must establish that the defendant’s breach of duty of care caused the plaintiff damage. Therefore, a patient who establishes that a healthcare professional breached his or her duty of care to inform that patient of a possible harmful side effect must then prove damage. The plaintiff must establish that he or she would not have consented to the medical intervention in question if warned of the possible harmful side effects. An Irish court considers this issue initially from the perspective of a reasonable patient: Would a reasonable patient have refused the intervention, if informed of the particular side effect in question? This objective approach yields to a subjective test where there is clear evidence to infer what the particular patient would have decided (Geoghegan v. Harris 2000). This objective approach makes it easy for a court to dismiss the particular patient’s complaint that he or she did not give informed consent because a reasonable patient would have given his or her consent. This approach could be considered paternalistic.

5.4 CONCLUSION

The right to information is imperative in relation to medical intervention. This right to information is found in different sources of Irish law and is far from uniform. These deficiencies in the law would make no difference where research on the practice of consent shows that in general the informed consent of patients has been obtained. However, there is limited research on this issue. The research that does exist is of concern. One report showed that only 56 percent of doctors and 34 percent of pharmacists told patients about the side effects of their medications (Irish Patients’ Association 2004a). Another survey carried out with patients in Ireland found that 47.7 percent were not given any information on the possible side effects of new medication that they received during their hospital stay (Irish Society for Quality and Safety in Healthcare 2005). The pilot study reported here also raises questions about the readability of patient information leaflets and their practical usefulness in informing a significant proportion of Irish patients.
6 RIGHT TO INFORMATION AND PERSONAL HEALTHCARE INFORMATION

Personal healthcare information is probably the most sensitive form of information that most patients want to keep private. A 2005 survey found that 80 per cent believed that it was very important that medical records remained private (Data Protection Commissioner 2005). Medical ethics and law provide that a healthcare professional owes a duty of confidentiality to a patient (Medical Council 2004 p29, Bord Altranais 2000, National Irish Bank v. RTÉ, 1998). The exact source of this legal duty is not certain, but may arise from the implied constitutional right to privacy (Kennedy v Ireland, 1987) and the fiduciary nature of the healthcare-professional relationship which implies trust and confidence (McNemey v. MacDonald, 1992).

Confidentiality is important to establishing the relationship between healthcare professional and patient because it facilitates a patient disclosing a suspected illness or condition. The protection of this information is essential to diagnosing and treating a patient. The duty of confidentiality and the right to information are connected.

6.1 REGULATION OF INFORMATION AND THE RIGHT TO INFORMATION

The regulation of information has been influenced by a number of important technological, economic and social factors over the past thirty years. These are:

- Technology facilitating the accumulation, storage, access and transmission of information with relative ease within a State and across State borders;
- The ability to use information and technology to make decisions concerning individuals and society;
- Greater appreciation of the commercial and social value of information;
- Protection of the rights of individuals; and,
- Transparency in how the State and its agents make decisions.

Any regulation of information involves a national and international response. The Council of Europe and the European Union have issued laws regulating personal "data". The Council of Europe has issued the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data 1981 and Additional Protocol to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data regarding supervisory authorities and transborder data flows 2001. The European Union issued Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

The purpose of these Council of Europe international treaties and the European Union Directive is to permit processing of data while at the same time protecting the rights of the person whose data is being processed. They adopt a similar approach to the regulation of data protection. Ireland implemented the treaties and the European Union Directive through the Data Protection Acts 1988 and 2003 (DP). The DP applies to anyone who processes data. Ireland also introduced the Freedom of Information Acts 1997 and 2002 (FOI). The FOI provides individuals and organisations with a right to access information held by the State and nominated State bodies provided this is consistent with the public interest and the right to privacy of individuals. The DP and FOI establish two independent bodies, the Data Protection Commissioner and the Information Commissioner with responsibility for interpreting and enforcing the principles of the relevant legislation.

A person who is dissatisfied with how another person is applying the DP may complain to the DP Commissioner. Similarly, a person who is dissatisfied with how the State or State bodies apply the FOI may complain to the FOI Commissioner.

6.2 DEFINING ASPECTS OF THE RIGHT TO INFORMATION

There are two aspects to the right to personal healthcare information. The first aspect is the right of a patient to have access to his or her personal healthcare information. The second aspect of the right is using the healthcare information for other purposes, which is not as well understood as the first.

6.2.1 Right of patients to access their personal healthcare information

This aspect of the right to information is clear and well understood. Personal healthcare information contained in the medical records of an individual includes the comprehensive medical history of an individual and is crucial to healthcare professionals involved in that individual’s current and future healthcare. It is clear that patients have an interest in accessing their personal healthcare information. However, there is no constitutional right in Ireland for a patient to have access to his or her personal healthcare information. There are nonetheless two other sources for that right in Ireland: statute and common law.

6.2.1.1 Statutory right of a patient to access personal healthcare information

Relevant statutory rights are found in the Data Protection Acts 1988 and 2003 (DP) and the Freedom of Information Acts 1997 and 2003 (FOI). These rights are expressed in similar terms. The FOI and DP rights will be discussed together and any differences between the FOI and DP will be highlighted. The most significant difference is that the FOI is only concerned with information held by the State and nominated State bodies. Therefore, the right of a public patient to access his or her healthcare information is regulated both by the FOI and the DP, while the right of a private patient to access his or her healthcare information is regulated solely by the DP.

The DP and FOI define personal healthcare information in slightly different ways. The DP defines “sensitive personal data” as including “the physical or mental health or condition” of an individual. The FOI defines “personal information” as including information relating to the “medical, psychiatric or psychological history of the individual”. It is suggested that nothing turns on this slight difference in definition.

The DP and FOI provide a patient with a right to a copy of the personal healthcare information. The DP does not entitle an individual with a right to the original file containing the information (Case Study 4/03 2003). A similar provision applies under FOI. The right of access is not absolute. Both the DP and FOI allow for refusing a patient access to his or her healthcare information. The most relevant restriction concerns refusing access to a patient where there is a risk that this access may cause harm to that patient. The DP provides that access may be refused, if it would be likely to cause “serious harm to the physical or mental health” of that patient (Data Protection Access Modification (Health) Regulations, 1989). A similar provision applies in relation to social work data (Data Protection (Access Modification) (Social Work) Regulations, 1989).

There are no reported DP Commissioner interpretations of this restriction. It is suggested that the person refusing access must be able to establish on balance that access would cause “serious harm”. Minor harm or upset would be insufficient.

The FOI approach to refusal has two significant differences. Firstly, a patient’s request may be refused where this “might be prejudicial” to the “physical or mental health, well-being or emotional condition” of that patient. It is suggested that the standard of “might be prejudicial” under the FOI is easier to satisfy than “likely to cause serious harm” under the DP. The DP Commissioner has interpreted this provision on two occasions. The FOI Commissioner emphasised that the person refusing access must be able to provide evidence as to how access “might be prejudicial” to the patient. This evidence must show that there is a real and tangible possibility of harm being caused to the patient as a result of granting access to that patient’s personal healthcare information (Case 99/189 2000, Case 00/0453 2002). A simple assertion of potential prejudice to a patient’s well being is insufficient.

Secondly, the FOI allows the person who possesses the information to refuse the patient direct access to that information. The FOI provides that the patient may nominate a healthcare professional who will be provided with the information and that nominated healthcare professional decides whether the patient should have access to the information. The patient may have the opportunity to obtain access to the information under FOI. However, a private patient does not have a similar right under DP. Private patients should have a similar right. This anomaly should be removed.

There are a number of ancillary DP and FOI rights, including the right to have corrections made to inaccurate or misleading information.

6.2.1.2 Common law right of a patient to access personal healthcare information

It is not clear whether a patient in Ireland has a common law right of access to his or her personal healthcare information. The common law right has been considered in Canada, England and Australia. These decisions may be relied on before an Irish court asked to consider this matter.

The common law position in Canada is that a patient does have a common law right to access his or her medical records. The patient is entitled to inspect and copy all healthcare information which the healthcare professional considered in administering advice or treatment. The treating healthcare professional has an obligation to provide this information. However, a patient's right of access to such
information is not absolute, and can be denied if the treating healthcare professional reasonably believes that it is not in the best interests of the patient to access this information. The burden of proof lies on the healthcare professional to justify refusing the request to access this information. Patients should have access to their medical records in all but a small number of circumstances. Access should be granted unless there is a significant likelihood of a substantial adverse effect on the patient’s physical, mental or emotional health or harm to a third party (Mehlhorn v. MacDonald, 1992).

The common law in England is similar but does not confer a common law right on the patient. The common law provides that the healthcare professional or service provider, as the owner of a patient’s medical records, is entitled to deny the patient access to them if it was in that patient’s best interests to do so. In R v Mid Glamorgan Family Health Services Authority, ex p Martin, 1995 the English Court decided that the local health authority could deny the patient in question unsupervised access to the records and refer to pass the information onto a healthcare professional nominated by that patient. The English Court held that a healthcare professional or service provider does not have an absolute right to deal with a patient’s medical records in any way it chooses and must act at all times in the best interests of that patient.

The common law in Australia provides that a patient has no common law right of access to his or her medical records. The records are the property of the healthcare professional (Iren v. Williams, 1996). Healthcare professionals in Australia have the discretion to decide whether to maintain the records, show the records or even destroy the records. However, the records cannot be used for profit or disclosed to unauthorised persons.

It is suggested that the Irish High Court would adopt the Canadian approach because the Irish constitutional right to privacy would influence the common law in Ireland.

6.2.2 Access and use of personal healthcare for purposes other than treatment of patients

The rationale for this second aspect of the right to information is that healthcare information relating to a patient is valuable outside the context of treating that patient. This information is also vital to bodies with responsibility for public health surveillance, disciplinary bodies of healthcare professionals, and evidence-based practice and clinical audit, teaching and training, and health planning to obtain consent for access to personal healthcare information.

The common law does permit access to personal healthcare information where the public interest clearly requires it. It is uncertain whether this exception could be invoked in relation to the purposes of public health surveillance, disciplinary bodies of healthcare professionals, evidence-based practice and clinical audit, teaching and training, and health planning. It would be better if access to such information was regulated by a statute that safeguards the privacy of patients and establishes in clear terms when and how patient healthcare information can be gathered.

The other exception relevant to DP and FOI occurs where the personal healthcare information is disclosed to prevent injury to, or damage to the health of, another person. The DP Commissioner upheld a health board’s decision to disclose the medical records of several patients of healthcare professionals for the purpose of a review because of concerns about this consultant’s practice (Case Study 103 2003). A serious public health concern could only be addressed by making this disclosure. Two other statutes deal with the disclosure of healthcare information:

- **Health (Protection of Information) Act 1997**: This permits the National Cancer Registry, the Minister for Health and Children, hospital or other body or agency participating in any cancer screening to request and gather personal healthcare information notwithstanding the principles of DP.
- **Disability Act 2005**: This precludes the processing of a person’s genetic data for the purposes of employing that person, issuing a policy of insurance or life assurance, a policy of health insurance or health-related insurance, an occupational pension, a retirement annuity contract or any other pension arrangement, or the mortgaging of property.

The Department of Health and Children’s report Health Information: A National Strategy (2004) explains that there is no system-wide framework for the governance of health information. The report states that the environment is not sufficiently supportive of some key activities or the protection of the interests of those involved, including individual privacy. The report recommends information governance legislation which will provide that:

- Personal health information belongs to the patient to whom it relates;
- Health professionals/agencies are the custodians of that information with legal responsibility for this information;
- Standard flows of health information are mandated which also protect patients’ rights; and,
- Access to healthcare information is allowed for other purposes including quality assurance and research with safeguards for patient privacy.

6.3 CONCLUSION

The right of a patient to access his or her personal healthcare information is adequately protected under the principles contained in DP and FOI with the DP and FOI Commissioners ensuring that these principles are upheld. However, there are significant deficiencies in the legal framework for regulating access to and use of personal healthcare information for purposes other than treatment of the patient.
7 RIGHT TO INFORMATION CONCERNING HEALTHCARE PROFESSIONALS AND SERVICES

7.1 RIGHT TO INFORMATION CONCERNING HEALTHCARE PROFESSIONALS

The right to information concerning healthcare professionals arises in three circumstances. A person or patient seeks information on whether:

- A person is a member of a healthcare profession;
- A healthcare professional is competent; and
- A complaint has been made in relation to a healthcare professional.

7.1.1 Membership of a healthcare profession

The right to information on whether someone is a member of a healthcare profession depends on whether the profession is regulated by statute. The following are examples of healthcare professions regulated by statute:

- Dieticians – Health and Social Care Professionals Act 2005;
- Pharmacists – Pharmacy Acts 1875 and 1953;
- Opticians – Opticians Acts 1956 and 2003;
- Dentists – Dentists Act 1985;
- Social Care Workers – Health and Social Care Professionals Act 2005;
- Social Workers – Health and Social Care Professionals Act 2005 and,
- Speech and Language Therapists – Health and Social Care Professionals Act 2005.

Each statute establishes a professional body whose function is to regulate its respective profession. Part of this involves establishing and maintaining a professional register. Some statutes permit registers of specialists within a profession. The professional body must register a person on the register where he or she satisfies certain conditions such as holding a specified qualification or having received training and passed examinations.

The right to information for patients and the public is achieved by requiring the professional body to publish the register and make it available to the public for inspection. For example, the Medical Practitioners Act 1978 requires the Medical Council to make the register available at the Council office during “office hours”. The Medical Council has gone further than its statutory requirement and publishes the register on its website allowing the public to search the register for a doctor by name. The Health and Social Care Professionals Act 2005 requires the registration boards to make their registers available for inspection by members of the public at all reasonable times and publish an electronic form of the register.

There is a risk that an individual may falsely claim to be a healthcare professional, such as nurse or psychologist, by using the title of that profession. A patient or member of the public can verify this by checking for that individual’s name in the register. Most statutes regulating healthcare professionals offer further protection to patients by making it a criminal offence for a person to claim to be a healthcare professional where he or she is not on the register. The Medical Practitioners Act 1978 as well as the other statutes by providing that it is a criminal offence for an individual to falsely represent himself or herself to be a registered medical practitioner. However, an individual does not commit a criminal offence by claiming to be a medical practitioner and not claiming to be registered in Ireland. Currently, the Medical Council has no powers to investigate a person who is not on the register and who ”practises medicine”.

In 2004, it was discovered that a US doctor, Dr Porter, who had been struck off the professional register in California for gross negligence and an Irish doctor, Dr Carmody, registered in the Medical Council’s register were treating terminally ill patients with a controversial cancer treatment. Research demonstrated that the treatment was ineffective (Moss 2003). The Medical Council found the Irish doctor guilty of professional misconduct and struck him off the register. However, the Medical Council could take no action in relation to the US doctor since he had not registered in Ireland, even though he had been struck off the register in California for gross negligence (Houston 2004). The Medical Practitioners Bill 2007 seeks to remedy this gap in the current law. An unregistered medical practitioner will commit a new offence where he or she:

- Practices medicine;
- Advertises that he or she is a registered medical practitioner; and
- Falsely represents that he or she is a registered medical practitioner.

The 2007 Bill confers the Medical Council with the power to investigate any person who is an unregistered medical practitioner and is suspected of practising or having practised medicine or suspected of claiming or having claimed to be a registered medical practitioner. The Medical Council must immediately inform the Gardai and the Minister for Health and Children of the results of this investigation where it provides the Council with reasonable grounds for believing that the person under investigation is or has practised medicine or has or is claiming to be a registered practitioner. The Minister for Health and Children has the power to seek an injunction in the High Court requiring the person to cease such activities.

In Ireland, there has been a significant growth in complementary and alternative therapies, such as acupuncture, aromatherapy, chiropractic, reflexology, and homeopathy. These complementary and alternative therapies are currently not regulated by statute. Therapists have established professional bodies on a voluntary basis. These professional bodies encourage, but cannot require, therapists to register. Patients and the public may inspect some of these voluntary registers. In May 2003, the Department of Health and Children established a National Working Group on the Regulation of Complementary Therapists to advise on the future regulation of alternative therapists. This Group recommended a two-pronged approach to regulation (National Working Group 2005). For herbs, acupuncturists and traditional Chinese medical practitioners, it recommended that statutory regulation be established along the lines of other healthcare professions. For all other complementary therapists, it recommended voluntary self-regulation by each profession, a system that would not be legally binding. Currently, patients of complementary and alternative therapists have no statutory right to inspect a professional register of any such therapists.

7.1.2 Information on competency

The registration of an individual on a healthcare professional register is evidence of that individual’s competency to practice. Membership of a profession imposes an obligation on each member to maintain his or her competency. For example, the Medical Council considers the maintenance of up-to-date knowledge and competence as a professional responsibility of every doctor. The Medical Council believes that this is best achieved by taking part in continuing medical education, continuing professional development, peer review and audit (Medical Council 2004 p17). An Bord Altranais imposes a similar obligation (Bord Altranais 2000). In Perez v. An Bord Altranais, 2005 the High Court confirmed An Bord Altranais’s decision to erase a nurse’s name from the register for being incompetent and not taking appropriate measures to develop and maintain the competence necessary for professional practice. This approach would also apply to the Medical Council. The Health and Social Care Professionals Act 2005 permits a complaint on the ground of “poor professional performance” which is defined as any failure of the healthcare professional to meet the standards of competence that may reasonably be expected of persons practising that profession.
The ability of any professional body to take disciplinary action for failure to maintain competency depends on a person making a complaint. Currently, a healthcare professional’s registration is not dependent on proving his or her competency on a regular basis. Moreover, the professional bodies do not have the requisite statutory powers to monitor a healthcare professional’s competency on a regular basis.

The Medical Council is seeking to address this deficiency by introducing Competence Assurance Structures (CAS) on a voluntary basis. CAS seeks to enhance the standard of care provided by all doctors and to protect the public from those who are performing poorly. This will be a continuous process through a doctor’s working life with a five-year cycle of accreditation.

CAS will achieve its goals in two ways. Firstly, CAS will set minimum levels of continuing medical education, regular peer review and clinical audit. Secondly, CAS permits doctors, patients and members of the public to voice concerns about the competency of a doctor to a Performance Review Committee that will investigate these concerns. This Committee will categorise these concerns as either those of less serious concern or those of more serious concern. Where the concern is less serious, questionnaires will be sent to colleagues, patients and other relevant people. The review may also involve an interview with the doctor and an audit of his or her continuing medical education. The Medical Council estimates that annually there will be about 500 of these less serious concerns.

Where the concern is more serious in comparison to international norms, a performance assessment team comprised of two peers and a non-doctor will undertake a more rigorous review. The assessment team has a variety of methods available to it to assess the doctor’s performance. The assessment team will send a report to the new Performance Committee of the Medical Council who will determine what action needs to be taken, including remediation or referral to a fitness to practise investigation if this is the only option that will protect patients. The Medical Council estimates that annually there will be about 50 of the more serious concerns (Medical Council 2006).

The major weakness of CAS is that it is voluntary. It is not certain whether the Medical Council could exercise its statutory powers to enforce CAS. The draft General Scheme of the Medical Practitioners Bill 2007 seeks to impose a duty on every registered medical practitioner to maintain his or her professional standards and competency. The Lourdes Hospital Inquiry Report recommends that the appropriate professional bodies will have the power to enforce standards on their members with the power to oblige practitioners whose skills are found wanting to attend for further training and provide the appropriate professional body with the financial means to be an effective overseer of the profession. The Medical Council would have a role in censuring non-compliant doctors (ibid. p.344). The Medical Practitioners Bill 2007 reflects the recommendations of the Lourdes Hospital Inquiry Report in two ways. First, the 2007 Bill seeks to impose a statutory duty on the Medical Council to ensure that registered medical practitioners maintain their professional competence. Second, the 2007 Bill allows the Medical Council to recognise medical education and training bodies to assist the Council in fulfilling its competence assurance role.

Competence assurance is not only an issue for the registered medical practitioners and the Medical Council. It is likely that similar statutory duties will be introduced to the statutory regimes of every healthcare profession.

In the context of the right to information, the issue arises as to whether patients and the public should have a right of access to information concerning a healthcare professional’s competency. The Lourdes Hospital Inquiry Report recommended that the Department of Health and Children introduce legislation to exclude clinical governance records and risk management clinical incident report forms from the application of the Freedom of Information Act 1997. The Lourdes Hospital Inquiry Report stated that unless these documents were excluded from the Freedom of Information Act 1997 they would likely not be created and opportunities for learning from mistakes would be lost (Department of Health and Children 2006 p.344).

The Information Commissioner, Emily O’Reilly, opposes this recommendation, believing that the existing exemptions in the Freedom of Information Act 1997 are sufficient to protect what is a very important public interest (Information Commissioners 2006). The Freedom of Information Act 1997 does not apply to certain documents where a particular public interest would be harmed by disclosure. The right of patients and the public to obtain this information is restricted.

Every competence assurance process document should not be exempt from Freedom of Information. There are two reasons for this. Firstly, a patient entrusts the healthcare professional with responsibility for his or her health and well-being. A patient should have access to information concerning the healthcare professional’s competence to discharge this responsibility. A patient should be entitled to decide, upon reviewing the information, to continue attending that healthcare professional or to attend another healthcare professional. Secondly, there is a significant power and knowledge imbalance in the healthcare professional–patient relationship. Any process that reduces such imbalance should be embraced.

The Medical Practitioners Bill 2007 provides that information obtained during the operation of the competence assurance scheme will be confidential. 7.1.3 Information on complaints related to a healthcare professional

An important duty of the healthcare professional bodies is the investigation of complaints that a healthcare professional is unfit to practice because of professional misconduct or his or her health. The right of a patient complainant to access information concerning complaints of misconduct differs depending on the healthcare profession.

The right to information of a patient complainant, other patients and members of the public is broader for professions regulated under the Health and Social Care Professionals Act 2005 than that pertaining under the Medical Practitioners Act 1978 and the Nurses Act 1985. The 2005 Act achieves this by specific provisions designed to enhance the right to information and the imposition of a general duty on the Health and Social Care Professionals Council. The Council is to make reasonable efforts to ensure that the complainant is kept informed of any decision relating to disciplinary action and that complaints are processed in a timely manner. The right to information arises in two stages of the complaint system. Firstly, there is the stage of the complaint in which the complaint is made until a decision is determined. Secondly, there is the imposition of a sanction by the professional body concerned.

7.1.3.1 First stage: Complaint made until decision determined

The right to information is similar where the complaint relates to a doctor’s or nurse’s alleged professional misconduct and/or alleged unfitness to practice for health reasons. The Fitness to Practice Committee (FPC) receives the complaint. The FPC decides whether there is a prima facie case for holding a fitness to practice inquiry. The right to information requires that a patient complainant should be informed of this decision and the reasons for it.

Where the FPC decides that there is not a prima facie case for holding a fitness to practice inquiry, the Medical Council or An Bord Altranais may direct the FPC to hold an inquiry. When the decision is to hold an inquiry, the Registrar sends a written notice to the doctor/nurse explaining the substance of the complaint, the nature of the evidence to be presented and the opportunity of that person or his or her representative to be present at the hearing.

Any complainant, including a patient, is not a party to the FPC inquiry. The Registrar of the professional body presents the evidence to the FPC. Despite the limited role of the complainant, the right to information of the patient complainant, other patients and members of the public in relation to the FPC is very restrictive. It is the practice of the Medical Council and An Bord Altranais to hold the inquiry in private (Medical Council 1999 p.15; Bord Altranais 2004 p.20). In Barry v. The Medical Council, 1998 the Supreme Court held that the Medical Council has discretion to hold the inquiry in public if all parties were agreed and if the FPC thought it was the proper thing to do. The same principle would apply to An Bord Altranais’s power to conduct the proceedings in private or public. A patient complainant will be entitled to attend the FPC inquiry where the inquiry is held in public. A patient complainant will be present at the inquiry hearing if he or she is called to testify as a witness at the inquiry. Patient complainants should have the right to attend the FPC inquiry to inform themselves of what transpires. Upon conclusion of the inquiry, the FPC informs the Medical Council or An Bord Altranais that the allegations of professional misconduct and/or unfitness to practice were or were not proven.

The Health and Social Care Professionals Act 2005 establishes two committees to deal with different complaints. The Health Committee will consider complaints concerning the impairment of the healthcare professional’s ability to practice because of a physical or mental ailment, an emotional disturbance or an addiction to alcohol or drugs. The Professional Conduct Committee will consider complaints relating to poor professional performance or professional misconduct.

The Preliminary Proceedings Committee assesses whether a complaint discloses a prima facie case for holding a Health Committee Inquiry or the Professional Conduct Committee Inquiry. It is unusual that the 2005 Act confers no express statutory right on the complainant to be informed of the outcome of the Preliminary Proceedings Committee. Where a Professional Conduct Committee Inquiry is being held, the right to information for the patient complainant, other patients of the healthcare professional and members of the public is extensive. The Professional Conduct Committee Inquiry will generally be held in public, unless the professional or complainant requests that the Committee hold all or part of the hearing otherwise, and the Committee is satisfied that
this would be more appropriate. However, the Health Committee Inquiry will generally be held in private unless the healthcare professional requests that the Inquiry be heard in public. The reason for the difference in approach is that the Health Committee is considering intimate, sensitive and private matters relating to the healthcare professional.

7.1.3.2 Second stage: Imposition of sanction

The relevant statutes recognize the interests of patients and the public in accessing information concerning the outcome of FPC action. The High Court has stated that:

Quite clearly, the common good can, and does, require the publication of facts… concerning a person who carries out duties or follows professions which may affect the public. In the case of a person practising medicine, the public have a clear and identifiable interest to be informed of a responsible view reached by his colleagues with regard to his standard of conduct or fitness. (IM v. The Medical Council, 1984 p500)

Where the FPC determines that the allegations are proven, the Medical Council or An Bord Altranais may erase, suspend or attach conditions to the healthcare professional’s registration or advise, admonish or censure the healthcare professional. Where the FPC determines that the allegations are not proven, the Medical Council or An Bord Altranais still has the power to attach conditions to a healthcare professional’s registration or advise, admonish or censure the healthcare professional.

The statute provides that the FPC’s findings and the Medical Council or An Bord Altranais’s decision may be published with the consent of the healthcare professional. The FPC’s findings and the Medical Council or An Bord Altranais’s decision may not be made public without the healthcare professional’s consent unless the FPC found the healthcare professional guilty of professional misconduct or unfit to practice. However, the High Court must decide whether to confirm the Medical Council or An Bord Altranais’s decision to erase, suspend or attach conditions to the registration of the healthcare professional. Therefore, the Medical Council or An Bord Altranais will not publish its decision despite the finding of professional misconduct until the High Court confirms the decision to erase, suspend or attach conditions to the registration of the healthcare professional.

The Medical Council and An Bord Altranais have adopted different approaches to publication in relation to erasing, suspending, advising, admonishing or censuring a healthcare professional:

- Ensuring or suspension: The Medical Council appears to automatically publish a decision to erase or suspend a doctor (1999 p20). An Bord Altranais considers publication on a case by case basis. The nurse is entitled to make representations to An Bord on the matter. However, a decision not to publish will only be made in cases of exceptional concern to Bord members (Bord Altranais 2003).

- Attach conditions: Any conditions attached to the retention of a doctor’s or nurse’s name are entered in the register and as such are available to any person who requests the register. However, An Bord seeks permission to publish the attachment of conditions to the registration where there was no finding made against the nurse (Bord Altranais 2003). It is not clear whether publication includes attaching conditions to the register.

- Advise, admonish or censure: The High Court does not have to confirm the Medical Council or An Bord Altranais’s decision to advise, admonish or censure a doctor, publication only occurs where a finding of professional misconduct is made and following the Council meeting at which the decision was made (Medical Council 1999 p20). An Bord Altranais will seek clarification, in writing, from the nurse as to whether he/she would like the FPC’s findings or An Bord Altranais’s decision to be published where there was no finding of misconduct, unfitness to practice, and An Bord Altranais advises, admonishes or censures the nurse (Bord Altranais 2003).

- Method and form of publication: The Medical Council publishes matters usually by inserting a notice in the legal notices section of the national and medical press (Medical Council 1999 p20). An Bord Altranais decides on the nature, content and format of the publication. Where the nurse holds or held registration with another regulatory body, An Bord may provide further information to be published only to that regulatory body. An Bord will publish the report of the FPC (made anonymous as appropriate) and the sanction. An Bord Altranais can use a press release, its newsletter, a letter or the Internet (Bord Altranais 2003). The 2004 annual report provided the names of those found guilty of professional misconduct (Bord Altranais 2004 p22-23).

- Complaintant: Where a finding is made against a nurse of professional misconduct and/or unfitness to practise by reason of physical or mental disability, An Bord Altranais will always inform the complainant of this finding. An Bord Altranais will determine the extent of information that the complainant will receive about the finding.

The Health and Social Care Professionals Act 2005 provides that the Health and Social Care Professionals Council’s ability to publish is expressed more clearly than that of the Medical Council or An Bord Altranais. The Council may, if satisfied that it is in the public interest to do so, advise the public when the Council decides to cancel, suspend, or attach conditions to a healthcare professional’s registration or admonish or censure that healthcare professional.

It is suggested that the transparency reflected in the 2005 Act will eventually be reflected in statutory provisions regulating the disciplinary powers of the Medical Council and An Bord Altranais. The Medical Practitioners Bill 2007 provides a similar right to information in relation to disciplinary proceedings for medical practitioners.

7.2 RIGHT TO INFORMATION CONCERNING HEALTHCARE SERVICES AND DISEASES

The right to information concerning healthcare services arises in three circumstances. A person or patient seeks information on:

- the quality of healthcare services;
- the availability of healthcare services; and,
- the prevalence of diseases and conditions.

7.2.1 Information concerning the quality of healthcare services

In the past two decades, healthcare organisations have enhanced their focus on accountability, outcomes and safety. Governmental and non-governmental agencies have taken it upon themselves to set guidelines and define standards, assess compliance with standards and continue to improve healthcare performance. It is perhaps surprising that with the escalating emphasis on healthcare quality, and the current legal environment that provides a variety of health related information through avenues such as data protection and freedom of information, there is no comprehensive legal framework for accessing information about quality of healthcare services.

Disclosure of such information is controversial. There are two interests that must be balanced. On the one hand, disclosure of information about the quality of healthcare services informs patients and members of the public, empowering them to make healthcare decisions. Disclosure of information may motivate healthcare service providers to improve the delivery of care. On the other hand, questions have been raised about the ability of patients and members of the public to put this information in context. For example, two healthcare institutions might publish their mortality rates. A patient or member of the public may prefer to attend the institution with the lower mortality rate. However, the information on mortality rates must be considered differently.

If, for example, the institution with the higher mortality rate is a hospice. Furthermore, it is possible that using mortality rates as a performance indicator may deter healthcare service providers from treating extremely ill patients.

Without elaborating on the context, it would be inappropriate to issue report cards or rating systems as it is difficult for the public to consider information in a vacuum. Furthermore, the potential for confusing the public with incomplete, poorly analysed, conflicting and even misleading information is enormous. The type of information contained in report cards and ratings systems varies dramatically. In 2000, a study outlined some of the 100 indicators used in healthcare reports (Marshall et al 2000). These indicators matters such as:

- overall in-hospital mortality rates,
- mortality rates for specific procedures,
- cardiac surgery intervention rates,
- percentage of caesarean operations performed,
- overall patient satisfaction rates,
- rate of complaints against providers, and
- doctors’ communication skills.

Although there is no framework for accessing information about quality of healthcare services, there are two legal methods for vindicating the right to information:

- The State has established a statutory review system for certain healthcare providers and allows the public access to this information. For example, the Mental Health Act 2001 provides for the appointment of an Inspector of Mental Health Services who has the power to review any public or private psychiatric facility. The Inspector must visit and review every approved facility at least once a year. The Inspector issues a report to the Mental Health Commission on the quality of care and treatment and other aspects of the services. The Inspector has various powers to enter and inspect premises, to obtain records, documentation and other information from the staff and to take evidence, relating to the inspection, under oath. The Inspector’s report is included in the Mental Health Commission’s Annual Report which is laid before both Houses of the Oireachtas. A number of other limited examples exist where information concerning the quality of healthcare services is published.

- Freedom of Information Acts 1997 and 2003 allow members of the public to seek information on public and State bodies including public healthcare providers.
Members of the public have used this legislation to access information on the increase in adverse reactions to certain vaccines or a health board’s inspection of private nursing homes. There are two difficulties with the approach of the Freedom of Information Acts 1997 and 2003. Firstly, the onus is on an individual to seek the information from the service provider and such provider can refuse access on certain grounds. The onus should be on the service provider to publish the information. Secondly, the legislation applies only to public healthcare service providers. An individual has no statutory right to information on the quality of private healthcare service providers.

The right of patients and the public to access such information needs to be improved, ensuring that such information is presented in its context.

7.2.2 Information concerning availability of healthcare services

There is no express constitutional right to receive information about the availability of healthcare services in Ireland. One tentative judicial pronouncement has been made that there is an implied right to receive information (SPUC v. Grogan, 1997) as a corollary to the implied right to communicate information (Attorney General and the Minister for Posts and Telegraphs v. Paperlink Limited, 1984). This right to receive information would apply to information concerning healthcare services. However, the likelihood of a patient incurring the significant legal costs in seeking an authoritative High Court declaration recognising such a right is extremely remote.

The Irish Courts have considered the right to receive information about the availability of abortion services in other States. In 1983, the Constitution of Ireland was amended to grant express protection of the right to life of the unborn child. In 1988, the Supreme Court held that there was no constitutional right to receive information about abortion services in other States. The Supreme Court prohibited the provision of such information because it would defeat the constitutional right to life of the unborn child (Attorney General (SPUC) v. Open Door Counselling Ltd, 1988). In 1992, the Constitutional protection afforded to the right to life of the unborn child was amended to permit the right to receive information on abortion services available in other States. This constitutional right is regulated by the Regulation of Information (Services outside the State for termination of pregnancies) Act 1995.

The State provides a significant amount of information about the availability of public healthcare services. Comhairle is a statutory body whose functions are:

- To support the provision of or to provide directly, independent information, advice and advocacy services so as to ensure that individuals have access to accurate, comprehensive and clear information relating to social services and are referred to the relevant services;
- To assist and support individuals, in particular those with disabilities, to identify and understand their needs and options and to access their entitlements to social services; and,
- To promote greater accessibility, co-ordination and public awareness of social services and of information, advice and advocacy services provided in relation to such services whether by a statutory body or a voluntary body.

Comhairle’s responsibilities include information on the availability of public healthcare services. It is not clear how the success of Comhairle is measured. For example, the State has been concerned at the public’s very low uptake on doctor-only medical cards, despite the perceived need for such cards. There is no right to information in terms of private healthcare services.

7.2.3 Information concerning prevalence of diseases and health promotion

Diseases: People have a right to information on the prevalence of two types of diseases: infectious diseases and cancer. The Health Protection Surveillance Centre (HPSC) aims to “improve the health of the Irish population by collating, interpreting and disseminating data in order to provide the best possible information on infectious disease. This is achieved through surveillance and independent advice, epidemiological investigation, research and training” (2007). The HPSC works in partnership with health service providers and similar organisations around the world, to provide up-to-date information for the effective control of infectious diseases. The HPSC publishes an annual report detailing the prevalence of certain illness in Ireland such as tuberculosis and meningococcal disease. Information about the prevalence of cancer can be obtained from the Irish National Cancer Registry, a State appointed body for monitoring cancer incidence in Ireland. The Registry maintains a database of information on cancer, and focuses especially on the number of cases and their prevalence. The information collected is used in research into the causes of cancer, in education and information programmes, and in the planning of a national cancer strategy to deliver the best cancer care to the whole population. There is a need for the State to accumulate and provide information on other significant diseases such as heart disease. The accumulation and dissemination of information assists in healthcare planning and making the public better informed.
Health information is increasingly seen as vital in an effective healthcare system. Informed consent gives patients a central role in healthcare decisions regarding their health and treatment. Such decisions require that patients have access to sufficient accurate information in a format they can understand. Whether or not the proposed right to information will improve patients’ ability to make informed decisions is unclear. The corollary to a right to information is a duty to provide information. Who might bear that duty is unclear. In addition, this report has shown that providing information is not sufficient to help patients make informed decisions.

For these reasons, the report recommends that the discussion focus on a patient’s right to be informed. The corollary to this right is a duty to help patients become better informed. Responsibility for this can be shared between healthcare professionals and patients. When decisions involve medications, the pharmaceutical manufacturers have a role in providing information. Such a right implies that the practical usefulness of patient information leaflets. It demonstrates the wide divergence between the law’s requirement for informed consent and the impact of what patients actually receive.

The right of patients to access their personal healthcare information under Irish law is very good. Some differences exist between the provisions of the Freedom of Information Acts 1997 and 2003 and the Data Protection Acts 1988 and 2003 which should be removed. However, legislation is needed to regulate access to and use of personal healthcare information for purposes other than treatment of the patient, while at the same time protecting the privacy of patients.

The right to information concerning healthcare professionals, services and products under Irish law is currently in transition. The law is seeking to provide patients and the public with greater rights of access to information about disciplinary procedures against healthcare professionals. There should be a right to information concerning the quality of healthcare services but with this information placed in its appropriate context. Medication information should be made available to patients. A right to information does not capture all of the important issues in this area. Patients do not need any type of information; they need information that is accurate and understandable. They need information that will inform them. The provision of a right to be informed better captures the issues of concern in this report. Healthcare professionals should be facilitated and encouraged both to remain current in the medication evidence relevant to their field of practice and to develop skills in communicating that information to patients in ways that inform them. It should also be recognised that healthcare professionals need time to communicate with and educate patients.

Pharmaceutical companies have a role in providing evidence-based information to healthcare professionals and patients, in the form of patient information leaflets. These should be available in a range of health literacy levels and languages. Patients should also be encouraged to see the importance of checking health information and accept a duty to inform themselves about the medications they are taking. The current prohibition on direct to consumer advertising of prescription medications should remain in force in Ireland.

Many of the areas discussed in this report lack empirical data. This is a significant limitation with the current situation. Research is needed to assess the average patient’s experience of the current legal provisions regarding information. It should be determined whether these legal standards are illusory or being honoured. Much research is needed into the health information available on the Internet and how Irish people interact with this. Strategies should be developed to encourage critical examination of health information, especially that found on the Internet and in other unregulated sources. Research is also needed into the effectiveness of strategies already in place to inform patients. Similarly, new initiatives should be tracked and measured to examine their effectiveness and impact. Only then will it become clear whether Irish patients are becoming more informed and whether this is helping to improve their health.

8.1 RECOMMENDATIONS

A right to be informed, rather than a right to information, should be conferred on patients in Ireland through appropriate legislation.

Healthcare professionals should be encouraged and resourced to spend time informing patients about their health and treatment options and allow sufficient time for questions and discussion. Patients should take seriously their responsibility to inform themselves about their health, their medications and any other treatments they might be receiving.

Pharmacies should seek to provide private areas for patients to discuss their medications with pharmacists.

8 CONCLUSION AND RECOMMENDATIONS

A legal right should be defined, comprehensive and accessible in order that a rights holder can confidently invoke the right and third parties can appreciate what is necessary to respect the right and their corresponding responsibilities and duties. The analysis of the legal right to information contained in this report shows that this right in its different contexts in Ireland does not satisfy this standard. Rather than focusing on a right to information, the report recommends that a right to be informed be conferred on patients in Ireland through appropriate legislation. This emphasises the importance of evidence-based, patient-friendly information.

The right to information and medical intervention under Irish law is excellent in some specialised areas such as clinical trials and mental health. The right to information does exist in relation to medical treatment. However, the right is inadequate and imperfect. Despite our pilot study’s limitations, it confirms the serious concerns we have about the practical usefulness of patient information leaflets. It demonstrates the wide divergence between the law’s requirement for informed consent and the impact of what patients actually receive.

The right of patients to access their personal healthcare information under Irish law is very good. Some differences exist between the provisions of the Freedom of Information Acts 1997 and 2003 and the Data Protection Acts 1988 and 2003 which should be removed. However, legislation is needed to regulate access to and use of personal healthcare information for purposes other than treatment of the patient, while at the same time protecting the privacy of patients.

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Pharmacies should seek to provide private areas for patients to discuss their medications with pharmacists.

Patient information leaflets for medications should be made available in a range of literacy levels and in different languages. Patients should be encouraged to have their literacy level evaluated so that they will know which leaflets will be most informative for them.

“Talking labels” and other innovative ways of promoting patient understanding of medication information should be encouraged and developed.

Direct to consumer advertising of prescription medications, as practised in the United States and New Zealand, should not be permitted in Ireland or the European Union.

Empirical research should examine the impact of all forms of advertising and information provision for healthcare products and services.

Pharmaceutical companies should continue to play a role in informing patients about their products via healthcare professionals and via objective, understandable information given with the medications, such as currently occurs with patient information leaflets.

High-quality, evidence-based health information should be made available on the Internet through the European Union and/or the Department of Health and Children. Such information should be accompanied by clear warnings of the dangers of self-diagnosis and self-treatment by patients.

Patients should be made aware of the importance of evaluating health information on the Internet and instructed on how to evaluate health information.

Educational strategies should be developed that encourage and develop patients’ skills in evaluating health information.

Research should be undertaken to evaluate Irish patients’ accessibility to health information on the Internet.

The right to information in relation to medical intervention under Irish law should be made more uniform to make informed consent as clear as it currently is in clinical trials.

The right of patients to access their personal healthcare information under Irish law is to be commended.

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The right of patients to access their personal healthcare information under Irish law is to be commended.

There is a need for legislation to regulate access to and use of personal healthcare information for purposes other than treatment of the patient and at the same time protect patients’ privacy.

The right to information about healthcare professionals, services and products under Irish law should continue to be developed.
Informing Irish Patients

9 Appendix I

9.1 Flesch-Kincaid Formula
The Flesch-Kincaid Formula assesses the average sentence length and the average number of syllables per word (Flesch 1974). The score indicates a grade level at which readers should be able to understand the text. The readability of the information leaflets is calculated using the following readability formulae.

The average sentence length (number of words / number of sentences) is calculated (L).

The average number of syllables per word (number of syllables / number of words) is calculated (S).

The grade level is found using the published formula = (L x 0.39) + (S x 11.8) – 15.59

9.2 SMOG Formula
The SMOG formula uses the frequency of words with three or more syllables to calculate both a grade level for reading and a reading age. This test often gives higher values because it is intended to predict the level necessary for 100 percent comprehension of the text. A SMOG grade of 13-16 indicates the need for college education to understand the text, 17-18 indicates the need for graduate training and 19 or higher indicates the need for a higher professional qualification (McLaughlin 1969 p645).

Three samples of 30 consecutive sentences are selected from each text. The number of words in each sample with three or more syllables is counted and the average determined (N).

The grade level = (Square root of N) + 3

The reading age = (Square root of N) + 8 years.

9.3 FOG INDEX
The Fog Index calculates how many years of education a reader would need to understand the paragraph, taking into account the number of words with three or more syllables. Its author pointed out that text “with a Fog Index of 13 or more runs the danger of being ignored or misunderstood” (Gunning 1968 p39).

Three samples of 100 words each are selected.

The average sentence length (L) is calculated (number of words / number of sentences).

The number of words with three or more syllables is counted. The average number of these words per sample is assessed (N).

The number of years of education required to understand the material is calculated as = (L + N) / 4.

9.4 CLOZE TECHNIQUE
The Cloze Technique has been shown to correspond well with a patient’s overall health literacy (Andrus 2002). The Cloze Technique is also useful since it is easy to prepare, administer and score.

A passage from the text being used is selected. For a Cloze test, the piece is normally about 300 words long. The first sentence is kept intact and thereafter, each nth word (usually the 5th) is deleted and replaced by a blank. The deleted words are listed at the end of the passage. The person being assessed is given the passage with blanks and the jumbled words and asked to fill in the blanks in the text with the appropriate words from the list. Each blank is marked as being either right or wrong. A Cloze test score of 60-100 percent means the information is understood; 40-59 percent, the information can be used but supplemental teaching may be needed; and below 40 percent, the information is not understood (Doak, Doak and Root 1996).

Each participant received both passages. From the Difené Suppositorie leaflet, a passage contained 49 blanks and there were 50 blanks in the passage from the Phenergan leaflet.

9.5 ETHICS
An application to conduct this part of the study was submitted to Dublin City University Research Ethics Committee and deemed exempt from review.

10. Bibliography (General)


Informing Irish Patients


informing irish patients


informing irish patients


11. BIBLIOGRAPHY (LEGAL)

11.1 CASES BEFORE IRISH COURTS
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Attorney General and the Minister for Posts and Telegraphs v. Paperlink Ltd [1984] ILRM 373
Barry v. The Medical Council [1998] 3 IR 387
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Geoghegan v. Harris [2000] 3 IR 536
I O’T v. B
Irish Times and Others v. Ireland
Jackson v. Harris [1996] 186 CLR 71
Jervis v. Mid Glamorgan Family Health Services Authority, ex p Martin [1995] 1 WLR 110

11.2 CASES BEFORE OTHER NATIONAL COURTS
Breen v. Williams [1996] 186 CLR 71
McInerney v. MacDonald [1992] 2 SCR 138
R v. Department of Health Ex parte Source Informatics Ltd [2001] QB 424
R v. Mid Glamorgan Family Health Services Authority, ex p Martin [1995] 1 WLR 110

11.3 CASES BEFORE THE EUROPEAN COURT OF HUMAN RIGHTS
YF v. Turkey, Application No 24209/94, 22 July 2003
Glass v. The United Kingdom, Application No 61827/00, 9 March 2004
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X and Y v. The Netherlands, Series A no. 91, p. 11, § 22, 26 March 1985
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11.4 ACTS OF THE OIREACHTAS (IRISH PARLIAMENT) AND BRITISH PARLIAMENT
Comhaithte Act 2000 (No 1 of 2000)
Control of Clinical Trials Act 1987 (No 27 of 1987)
Control of Clinical Trials and Drugs Act 1990 (No 17 of 1990)
Data Protection Act 1988 (No 25 of 1988)
Doctors Act 1985 (No 9 of 1985)
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Health and Social Care Professionals Act 2005 (No 27 of 2005)
Medical Practitioners Act 1978 (No 4 of 1978)
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Opticians (Amendment) Act 2003 (No 22 of 2003)
Pharmacy Act (Ireland) 1875 (38 & 39 Vict c 57)
Pharmacy Act (Ireland) 1875 Amendment Act 1890 (53 & 54 Vict c 48)
Pharmacy Act 1951 (No 30 of 1951)
Regulation of Information (Services outside the State for termination of pregnancies) Act 1995 (No 5 of 1995)

11.5 STATUTORY INSTRUMENTS
European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (No 190 of 2004)
European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (No 158 of 2006)
Medical Preparations (Advertisting and Sales) Regulations 1984 (SI No 210 of 1984)

11.6 BILLS OF THE OIREACHTAS
Medical Practitioners Bill 2007

11.7 DECISIONS OF THE INFORMATION COMMISSIONER

11.8 DECISIONS OF THE DATA PROTECTION COMMISSIONER

Medical Preparations (Advertising) Regulations 1993 (SI No 76 of 1993)
11.9 EUROPEAN DIRECTIVES


Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data OJ L 281, 23/11/95 p 31.

Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use OJ L 121, 01/05/2001 p 34.


11.10 EUROPEAN TREATIES


11.11 UNITED STATES LEGISLATION


Sherley Amendment Act 1912, Ch. 352, § 8, 37 Stat. 416 (1912)

11.12 INTERNATIONAL TREATIES AND CONVENTIONS


