



Why Greater Freedom of Patient Information in European Healthcare Could Save Lives and Money

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Centre for the New Europe

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Executive Summary

- The proposal of this paper is that more and better patient information should be encouraged throughout the European Union.
- Europeans should have the right to receive full information about health care products from all available sources, including the pharmaceutical companies that research, develop and manufacture them under intense regulatory scrutiny.
- The paper asserts that far from increasing health expenditure by European governments, greater freedom of information in healthcare would likely help to save many hundreds of millions of Euros every year.
- The paper argues that the personal computer has changed the world. As millions of people throughout developed countries increasingly have computers in their homes and places of work, so it has become possible to share information on a larger scale than ever before.
- With the emergence of the Internet in the 1990s, a vast wealth of information has become directly accessible to anyone with the right technology and the will to go looking.
- By March 2000, about 18 per cent of households within the European Union had Internet access. This rose to 38 per cent in December 2001. By this time, almost half the entire European Union population over the age of 15 was using the Internet at home, or at school, or at work.
- Again, the world in which traditional state healthcare systems were established has largely gone. Physicians could then be presumed able to prescribe appropriately and represent individual patient interests. Doctors are now torn between the financial constraints governments place on them and the need to act in the best interest of their patients.
- Today, this explosion of information is accelerating. The pharmaceutical companies are bringing out new products on an almost weekly basis – to fight cancer, heart disease, and even ageing itself. An exponential growth in the number of web pages has now led to a situation in which people routinely try to diagnose their own conditions and research the most appropriate treatments before they visit a physician.
- In a survey conducted in 2001 for the journal *General Practitioner*, nearly nine out of ten physicians thought patients were better informed than they were ten years ago, and 72 per cent said the Internet had increased the number of patients who self-diagnosed or demanded specific treatments.
- Today, medical professionals are no longer seen as infallible gatekeepers between patients and the pharmaceutical suppliers. The old relationship – based on condescension from one side and respect from the other – is breaking down. Instead, medical professionals are increasingly seen as brokers. Patients demand. The pharmaceutical companies supply. The Physician brings them together by signing the

appropriate prescription. When what is demanded is thought inappropriate, the physician may no longer flatly deny, but must instead persuade. And often, when persuasion fails, an increasingly diverse healthcare sector in all European countries, never mind America, allows disgruntled or unconvinced patients to seek a second opinion.

- Given this reality, the authors of this paper propose that a great deal of misplaced and increasingly irrelevant health censorship in Europe be formally removed.
- The effect of this proposal would be to allow a range of healthcare organisations to better inform patients directly, rather than, as at present, exclusively provide information to physicians and other medical professionals. People would thereby be given access to much more information about the availability and effects of all products and procedures, and be put into the position of being able to discuss their medical options with the professionals from a basis of shared information. This would go far to completing the cultural revolution in health care that is turning patients into health consumers.
- Giving individuals full access to pharmaceutical information might in some cases keep them entirely from visiting their physicians. It could also reduce time spent on those visits still made.
- The paper concludes by asserting that the citizens of a democracy have the right to know about products that might save or at least improve their lives. Overall, the cost savings from greater freedom could be substantial and easily in excess of 437 million Euros a year.
- For the authors, European citizens must have the right of full access to information about their health, medical conditions and the availability of treatments. As such, the authors note that this right may soon be actionable under Article 11 of the Charter of Fundamental Rights, published by the European Union in 2002.

Introduction

The proposal of this paper is that better patient information should be encouraged throughout the European Union. Europeans should have the right to receive full information about health care products from all available sources, including the pharmaceutical companies that research develop and manufacture them under intense regulatory scrutiny.

We propose that the authorities throughout the European Union should accept that a regulatory system that was not incompatible with 20th century medical practice is not compatible with the medical practice of the 21st century. It should be accepted by all that the status of medical professionals has changed. It has not collapsed by any means. But while they are still seen – and rightly seen – as indispensable sources of advice, physicians are no longer seen as oracles. They are expected to converse with their patients almost as equals – and perhaps sometimes even to learn from them. Given this changed technological and cultural basis of healthcare, the regulatory superstructure must also change.

We do not here propose that products should be advertised for direct sale to the public. Very few people would consider it sensible to return to the right of self-medication taken away after the Great War. But we do propose that European Union regulations should be changed so that the pharmaceutical companies are able to offer on their web sites and in any other medium full information to all about the availability of their products and about the beneficial effects and side effects of their products. We propose that greater freedom of information should be permitted for all medical conditions, and not just the limited number proposed by the European Commission. We propose that citizens of the European Union should have the same right to full information about products as American citizens now have.

If adopted, it is estimated that global healthcare costs in the United Kingdom could fall by as much as £109 million per year, and throughout the European Union as a whole by as much as 437 million Euros.

Historical Background

Until the 20th century, physicians were regarded as optional intermediaries between patients and the suppliers of medicines. This situation rested on two facts. First, very few people had access to or could afford the services of a qualified physician. Second, there were few legal controls on the supply of pharmaceutical products. Physicians might be consulted, and might recommend specific doses of specific products. But such consultations, where they occurred, were regarded as part of a range of options in which self-medication had an accepted place, and individuals were expected to seek advice from a variety of sources.

To see how normal it was for individuals to rely on non-professional advice, see this by Thomas De Quincey:

From an early age I had been accustomed to wash my head in cold water at least once a day; being suddenly seized with tooth-ache, I attributed it to some relaxation caused by an accidental intermission of that practice; jumped out of bed, plunged my head into a basin of cold water, and, with hair thus wetted, went to sleep. The next morning, as I need hardly say, I awoke with excruciating rheumatic pains of the head and face, from which I had hardly any respite for about twenty days. On the twenty-first day I think it was, and on a Sunday, that I went out into the streets; rather to run away, if possible, from my torments, than with any distinct purpose. By accident, I met a college acquaintance, who

recommended opium.... I saw a druggist's shop. The druggist (unconscious minister of celestial pleasures!), as if in sympathy with the rainy Sunday, looked dull and stupid, just as any mortal druggist might be expected to look on a Sunday; and when I asked for the tincture of opium, he gave it to me as any other man might do! and, furthermore, out of my shilling returned me what seemed to be a real copper halfpenny, taken out of a real wooden drawer.¹

The Pharmacy Act 1868 confined the right in mainland Britain to sell strong pharmaceutical products to members of the Pharmaceutical Society of Great Britain, but placed no controls on the manner of sale to the public. Certainly, there were no special controls on the advertising of any pharmaceutical product. Such controls as did exist were part of the general laws of contract and tort.

Indeed, one very famous law case can stand as illustration for the normal approach in Britain to the advertising of pharmaceutical products. In 1892, the Carbolic Smoke Ball Company placed an advertisement in the newspapers for a product guaranteed to preserve all who used it properly from contracting influenza. So sure was the company that it offered £100 for anyone who used the product as directed and still caught influenza. The product appears to have been useless, as it was little more than a ball of charcoal in a container that had to be lit and carried round and periodically inhaled. A Mrs Carlil bought the products, was accepted by all sides to have used it as directed, and still caught influenza. She claimed her reward, and the case went into court – eventually reaching the law books where it remains one of the leading cases on consideration.² Pharmaceutical products were routinely advertised direct to the public, and people were expected to form their own opinion on their usefulness, with or without qualified advice.

In many European countries, the authorities exercised a greater degree of regulation. But the general situation was much the same as in Britain - that individuals were considered to have primary responsibility to manage their health care, and were left to choose whatever course of treatment they might think appropriate, and to seek and use such information as might be offered. The usual means of selling pharmaceutical products was direct-to-consumer advertising.

This situation changed considerably during the first half of the 20th century. In the first place, medical progress brought a continual and accelerating wash of new pharmaceutical products onto the market. These were far more specific than had been the case previously, and usually far more effective. They were also far more dangerous if not used exactly as directed. To be sure, opium and its derivatives are highly addictive, but seldom kill or cause serious disability unless taken in very large doses. But products such as insulin and Digitalis and Salvarsan and Penicillin can be deadly to those who do not need them, and often in themselves have dangerous side effects unless used exactly as directed. As medicine became more effective, so the need for medical advice before treatment became less a luxury and more a necessity.

With this went an altered conception of medical authority. In 1900, medical professionals enjoyed high status. But, as said, their services were regarded as optional. In a sense, they were rather like plumbers now are. It was seen as desirable to consult them, but not at all essential. By 1950, they had largely replaced ministers of religion as dispensers of advice and comfort. Only they could be trusted to look at the bewildering array of treatments now

¹ Thomas De Quincey, *Confessions of an English Opium Eater* (1832), available at: <http://nepenthes.lycaum.org/Ludlow/Texts/Opium/pleasure.html> (Checked September 2004)

² *Carlill v The Carbolic Smoke Ball Company* [1892] 2 QB 484 (Queen's Bench Division) - <http://www.leeds.ac.uk/law/hamlyn/carlill.htm> (Checked September 2004)

available and say which one was most suitable for any individual patient. What the doctors said must be true, it was generally believed. What they did not endorse should be ignored.

The same was true of professional authority in general. In 1947, Douglas Jay, a Minister in the British Government said:

[I]n the case of nutrition and health, just as in the case of education, the gentleman in Whitehall really does know better what is good for the people than the people know themselves.³

While this was derided by some, it can be taken as a statement of what for many was a self-evident proposition. Indeed, this rise in the status of health professionals was based on an objective improvement in the quality of service. According to Brian McAvoy:

somewhere between 1910 and 1912 in this country.... a random patient, with a random disease, consulting a doctor chosen at random, had for the first time in the history of mankind, a better than fifty-fifty chance of profiting from the encounter.⁴

Add to this, changes in the availability of pharmaceutical products. From about 1920, all European countries passed laws that at least regulated the supply of strong pharmaceutical products. The main purpose of these laws was to prevent the recreational use of narcotics and stimulants – to prevent the sort of experimenting that had turned De Quincey into a notorious and hopeless addict. Their other and probably unintended effect was to turn medical professionals into gatekeepers between the public and suppliers of pharmaceuticals. Access remained unlimited for a wide range of general and fairly weak products. But access to the new and more powerful specifics needed to cure or alleviate serious conditions was routinely channelled through the medical professionals who were empowered to allow access through signed prescriptions or to refuse access altogether.

The modern structure of pharmaceutical access was completed by the growth of state involvement in the provision of healthcare. In 1900, physicians in most European countries enjoyed a high status, as said, but held much the same position as plumbers now do. They offered their services to the public at such prices and on such other terms as market conditions dictated. By 1950, they were a professional order working for the State or for some agency privileged by the State. Most people did not pay for medical services directly, but either through their taxes or through insurance premiums in some scheme at least regulated by the authorities.

Such has been the general situation since around 1950. We have an increasingly complex and dynamic pharmaceutical market in which it has been reasonable to see untrained members of the public as incompetent to make informed choices about products, and we have a medical profession expected and empowered by law to make their choices for the public. Given these facts, there was little reason for the pharmaceutical companies to bother with direct advertising or for that matter, the provision of any information directly to health consumers. All advertising is expensive, and advertising to those legally prevented from buying products makes no sense – especially when these people mostly accept that they really are not

³ Douglas Jay, *The Socialist Case*, London, Victor Gollancz, 1947, p. 258. Worth stressing here is that this was not some casual remark pounced on by a journalist and quoted out of context. It comes from the second revised edition of a book first published ten years previously, and is therefore the product of some consideration.

⁴ Brian McAvoy, *Models of Primary Health Care: The U.K. Experience*, paper presented to the 2000 National Conference of the Doctors Reform Society in Melbourne, 21 October 2000 – available on line at: http://www.dr.org.au/new_doctor/74/mcavoy.html (checked September 2004)

competent to decide on the usefulness of the products in question. Even without legal controls, advertising would inevitably have become a highly specialised conversation between the pharmaceutical companies and the medical profession.

But, just for the sake of completion, advertising controls were imposed in many European countries. These are now codified in the commercial law common throughout the European Union. Directive 2001/83/EC on the Community code relates to medicinal products for human use. This Directive prohibits the advertising of prescription only medicines to the general public. Indeed, it goes further in suggesting that rules are needed for all pharmaceutical products, whether or not prescribed:

Advertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered. Advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria which ought to be defined.⁵

Even before this blanket prohibition came into force within the European Union, many national jurisdictions had adopted into their product liability laws some variant of the American “learned intermediary rule”, whereby pharmaceutical suppliers were under a duty to warn only the physician intermediary, not the patient. Such rules essentially immunised the pharmaceutical manufacturer in most failure-to-warn cases. Injured, uninformed patients were expected to proceed against the doctor for negligence, typically for lack of informed consent.⁶

Back to the Future

Historians hardly ever think of a century as beginning in their first chronological year. Instead, they fix on some important event somewhat before or after. Thus, the 18th century begins in 1714 or 1715, the 19th in 1789, and the 20th in 1914. When future historians will settle the first year of the 21st century is still in doubt. It might be with the collapse of Soviet power in 1989, or the American bombings of the 11th September 2001. But a fair contender seems to be September 1981, with the first release of MSDOS. This must certainly be seen as a key date in the rise of the empowered individual.

Of course, no important social and cultural fact has only one cause. It was in the 1970s and even in the 1960s when public doubts first emerged about the unlimited competence of the medical profession to choose the best treatments for patients. The range of pharmaceutical

⁵ The Directive is to be found at http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00670128.pdf. (Checked September 2004). The quoted words are from para. 45 of the Preamble. See also Title VIII, on Advertising, and this from the preamble: “(44) Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities (2) prohibits the television advertising of medicinal products which are available only on medical prescription in the Member State within whose jurisdiction the television broadcaster is located. This principle should be made of general application by extending it to other media.

⁶ For a full discussion of the American rule, see David J. Cooner, *The Intersection of Madison Avenue and the Learned Intermediary Doctrine*, http://library.lp.findlaw.com/articles/file/00395/008727/title/Subject/topic/Products%20Liability_Learned%20Intermediary%20Doctrine/filename/productsliability_1_904 (Checked September 2004). David J. Cooner is a partner in the Firm of McCarter & English, LLP, and a member of the Firm's Products Liability Group. His practice has focused on representing medical product manufacturers, pharmaceutical and chemical companies, and other companies in product liability matters, as well as representing healthcare professionals and business entities in a wide range of litigated matters.

products had by then grown so large, and so often changed by new discoveries, that general practitioners were no longer able to know in all cases what was best. Perhaps they still knew more than the uninformed public, but they were evidently not omniscient. They were seen to have made mistakes. There was the thalidomide scandal of the early 1960s, when physicians very widely prescribed a drug that had not been properly tested. Again, in the 1970s, they were shown to have put too much faith in the power of antidepressant drugs to treat the boredom and unhappiness of the lonely. It was also increasingly suspected that they were refusing to prescribe treatments for conditions like cancer that might be more effective than those commercially available.

It must be emphasized that there has been no general loss of trust in medical professionals. Every year the polling organisation MORI asks people in Britain to what extent they trust various professionals. Every year, medical professionals are shown to be the most trusted group – in 2004 scoring a trust rating of 92 per cent.⁷ At the same time, though, there has been a fall in trust. In May 2001, the British Government's National Audit Office announced that, as of the previous March, there were 23,000 clinical negligence claims outstanding, costing an estimated £3.9 billion. Both the number and value of claims were rising: between 1990 and 1998 the number of new claims rose by 72 per cent.⁸ The number of claims is rising partly because of changes in law and procedure that make it easier to sue than was once the case – but also because physicians have lost some of the professional aura in which ordinary patients used to regard them.

There is no doubt that the world has changed. The world in which national healthcare systems were established has gone. Physicians could then be presumed able to prescribe appropriately and represent individual patient interests. But over the past few decades, national healthcare systems have undergone radical change. Doctors are now torn between the financial constraints governments place on them and the need to act in the best interest of their patients. And, aside from the financial pressures, the explosion of medical information has meant that doctors can never be knowledgeable and expert in more than a few clinical areas.

And this explosion of information is accelerating. The pharmaceutical companies are bringing out new products on an almost weekly basis – to fight cancer, heart disease, and even ageing itself. No general practitioner can be expected to know about more than a fraction of this research.

For all these reasons, medical professionals cannot be left in complete charge over the needs of their patients. They need help – and help often comes best from the patients themselves. They have the strongest interest in researching the latest treatments for their conditions.

Public involvement, though, was limited by the lack of access to information. The main sources were:

- newspapers and magazines (most of which have long carried extensive copy about health issues);
- broadcasting;
- popular books;
- voluntary organisations and support groups.

⁷ Trust In Doctors, 23 March 2004, available at <http://www.mori.co.uk/polls/2004/bma.shtml> (Checked September 2004)

⁸ Simon Crompton, "Trust me, I'm a doctor", *The Times*, London, 8th May 2001.

Each of these sources had its disadvantages. Newspapers and magazines have always been sporadic in their reporting of issues. They cover issues that are already in the news. They have a tendency for uncritical reproduction of material submitted by special interest groups. They have an interest in promoting alarm and even panic. They often aim for the sensational at the expense of the true. It is the same with broadcasting – with the added problem that programme makers have still more of a tendency to simplification of issues, and there was until recently no regular means of making additional and more specific material available for those wanting to go beyond an initial report. As for books about medicine and health, these have always ranged between the scholarly and the worthless, and the public has often been unable to distinguish between the two. The only medium in which information about the full range of treatments actually or potentially available was to be found was an often physically inaccessible literature in the medical and scientific journals, and this was generally available by expensive subscription and written in a language that required a scientific education to be understood.

Voluntary organisations and support groups have frequently done very good service as transmitters of information. But it has not always been easy to find them or even know about their existence.⁹

The personal computer changed all this. As millions of people throughout the developed world bought computers for their homes, it became possible to share information on a larger scale than ever in the past. At first, information was shared on floppy disks sent through the post. With the emergence of the Internet in the 1990s, though, a vast wealth of information became directly accessible to anyone with the right technology and the will to go looking. By the opening of this century, falling prices in the information technology market had enabled around half the population in the developed world to get access to the Internet. By March 2000, about 18 per cent of households within the European Union had Internet access. This rose to 38 per cent in December 2001. By this time, almost half the entire European Union population over the age of 15 was using the Internet at home, or at school, or at work.¹⁰

An exponential growth in the number of web pages has now led to a situation in which people routinely try to diagnose their own conditions and research the most appropriate treatments before they visit a physician. It is common for patients to visit their general practitioner, describe their symptoms, suggest a diagnosis, and then to hand over a set of pages printed from the web that recommend a treatment.

In a survey conducted in 2001 for the journal *General Practitioner*, nearly nine out of ten physicians thought patients were better informed than they were ten years ago, and 72 per cent said the Internet had increased the number of patients who self-diagnosed or demanded specific treatments.¹¹

⁹ Summarised from *HealthWatch Position Paper on Direct to Consumer Advertising of Prescription Medicines*, HealthWatch Position Paper, 3rd December 2002. Available at <http://www.healthwatch-uk.org/dtc.pdf> (Checked September 2004)

¹⁰ figures from Erkki Liikanen, a Member of the European Commission, writing in “Should Pharmaceutical Companies Provide the Public with More Information on Prescription Medicines?”, a Patientview Report, June 2002.

¹¹ Simon Crompton, “Trust me, I’m a doctor”, *The Times*, London, 8th May 2001.

Physicians joke about this. Often, they complain about it. Doubtless, some wish it were not so. But there is nothing they can do about it. So far as it can be measured, the status of medical professionals has fallen in recent years. They are not trusted to always make the right diagnosis. They are not trusted to know infallibly the right treatment. Because of budgeting constraints imposed by state healthcare systems, they are often not trusted to prescribe the right treatment even when they know what this might be. At the same time, more and more individuals have access to alternative sources of information, and are not embarrassed to insist on discussing medical matters on an equal basis with the medical professionals.

The medical professionals are no longer seen as infallible gatekeepers between patients and the pharmaceutical suppliers. The old relationship – based on condescension from one side and respect from the other – has broken down. Instead, medical professionals are increasingly seen as brokers. Patients demand. The pharmaceutical companies supply. The Physician brings them together by signing the appropriate prescription. When what is demanded is thought inappropriate, the physician may no longer flatly deny, but must instead persuade. And often, when persuasion fails, an increasingly diverse healthcare sector in all European countries, never mind America, allows disgruntled or unconvinced patients to seek a second opinion .

The medical world, then, has seen a cultural revolution in the past few years. Patterns of deference and acceptance of monopolistic access to information that were almost ingrained as recently as 1990 have been eroded. We are visibly returning to the more diverse medical environment of the past. Increasingly, people who visit physicians are less to be regarded as patients than as health consumers. They want from their physicians the same levels of service and interactive consultation as they take for granted from their financial advisors, hairdressers or travel agents.

The Proposal

As already said, the authors of this paper propose that a great deal of health censorship in Europe should now be abandoned. The effect of this would be to allow a range of healthcare organisations to better inform patients directly, rather than, as at present, exclusively provide information to physicians and other medical professionals. People would thereby be given access to much more information about the availability and effects of all products and procedures, and be put into the position of being able to discuss their medical options with the professionals from a basis of shared information. This would go far to completing the cultural revolution in health care that is turning patients into health consumers.

The European Union itself has proposed something similar. In 2001, the European Commission proposed changes to the regulations on direct-to-consumer information. According to Erkki Liikanen, the Commissioner for Enterprise and the Information Society, the Commission was proposing a limited relaxation of the rules. He emphasised:

This is not direct to consumer advertising. We are not introducing advertising for prescription drugs. What we want to do is, as a test case, with respect to three specific disease groups, to make sure that validated and patient orientated information can be made available – when this information is requested by patients or groups of patients.

The diseases chosen: diabetes, AIDS and asthma are diseases which are long-term and chronic, where there is a strong and specific patient demand for information, where the types of drugs used are the

same throughout Europe, and in which the results of the 5-year pilot should be relatively easy to monitor.¹²

However, this was rejected the following year by the European Parliament. This was not the end of the matter. In a Directive of 2004, the European Commission states:

Within three years of the entry into force of Directive 2004/726/EC, the Commission shall, following consultations with patients' and consumers' organisations, doctors' and pharmacists' organisations, Member States and other interested parties, present to the European Parliament and the Council a report on current practice with regard to information provision —particularly on the Internet —and its risks and benefits for patients. Following analysis of the above data, the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non-promotional information on medicinal products and other treatments and shall address the question of the information source's liability.¹³

Doubtless, there will be changes made.

Steps have already been taken in at least the United Kingdom towards turning medical consultations into informed conversations. In particular, prescribed medicines are no longer labelled *the tablets* and *take as directed*. Instead, the product is named and specific dosage instructions are given. In addition, a patient information leaflet (PIL) now accompanies products dispensed by a pharmacist on prescription. It explains the purpose of the drug, describes its constituents, warns about contra-indications and expected side effects and lists information that helps track down the cause of an allergic reaction.

Knowledgeable consumers can also ask their doctors for an SPC, or Summary of Product Characteristics. This provides detailed information on the product and is intended to assure EU-wide consistency in indications, dosage and use of medicines. In the UK, it is not legal for a pharmaceutical company representative to promote a product without first giving a copy of the SPC to the doctor, so that factual information can put the promotion into perspective.

In the United States and New Zealand which have actual experience of direct to consumer advertising, it is increasingly common for patients and physicians to discuss medications on a fairly equal basis. In the United States, half of the physicians approached in a major survey felt “a little” pressure to prescribe what their patients requested, and six per cent felt “a lot” of pressure.¹⁴

The Benefits of Freedom of Information

Allowing freedom of patient information within the European Union would bring a number of benefits.

¹² News Release, Brussels, 18 July 2001 Mr Erkki Liikanen, Member of the European Commission, responsible for Enterprise and the Information Society, Commission's proposal to review EU pharmaceutical legislation - http://pharmacos.eudra.org/F2/review/doc/speech01_354_en_ppt.pdf (Checked September 2004)

¹³ Directive 2004/27/Ec Of The European Parliament And Of The Council Of 31 March 2004, Amending Directive 2001/83/EC On The Community Code Relating To Medicinal Products For Human Use: Title VIII a, Information And Advertising Article 88a - http://pharmacos.eudra.org/F2/review/doc/final_publ/Dir_2004_27_20040430_EN.pdf (Checked September 2004)

¹⁴ Michelle M. Mello, Meredith Rosenthal, Peter J. Neumann, “Direct-to-Consumer Advertising and Shared Liability of Pharmaceutical Manufacturers, *Journal of the American Medical Association*, January 2003, Vol.289, No.4, pp. 477-81.

Good Information Drives out Bad

The Internet is a source of information. Sadly, much of the information offered about matters of health is false or even dangerous. Some websites, for example, recommend Prozac as an appetite suppressant.¹⁵ It is a powerful and sometimes counter-productive anti-depressive. It should only be prescribed for specific types of depression, and then under medical supervision, and even then for short periods. Anyone who thinks it can help with dieting may be misinformed. Sadly, Eli Lilly, the manufacturer of the product, is not allowed to publish a word within the European Union about the correct uses of Prozac.

Again, there are websites that denounce the products of the pharmaceutical companies and instead recommend products that may be useless or actually harmful. These products include psychic surgery, faith healing, laetrile, and much else.

In 2004, the *Journal of Medical Internet Research* published a survey of websites providing information on complementary and alternative medicine (CAM). The researchers found that:

We found that most CAM Web sites were potentially harmful either by displaying statements which could cause harm, or by omitting vital information. However, our data suggest that available technical quality criteria fail to identify potentially harmful information online.

We found that one quarter of CAM Web sites present information that may cause physical harm if acted upon. These sites encouraged consumers to avoid conventional therapy, presented information on products that may be directly toxic, or presented information on products that may cause interactions with conventional medications. This is potentially dangerous because consumers have easy access to CAM products online and act upon what they see on the Internet.

Almost all (97%) CAM Web sites omitted vital warnings, drug interactions, contraindications, or adverse reactions. This is concerning because many consumers perceive "natural" products as safe. Further, many herbs that may be safe when used alone interact with conventional medications.¹⁶

The pharmaceutical companies are often prevented by law from replying in detail to these claims, and from offering their own opinion about the effectiveness and best use of their own products. Anyone can set up a website to claim that Viagra can cure lung cancer. Pfizer, which developed the product, is not allowed within the European Union to say on its own website how it should best be used.

The rise of the Internet has turned a set of regulations devised to protect patients into one which makes them into victims of asymmetric information. Falsehoods are to be found everywhere. All that is now regulated is the truth. Our proposal would improve the health and general well-being of all the peoples of the European Union, by enabling the purveyors of false information to be authoritatively refuted.

¹⁵ See, for example, <http://helpuniversity.com/pharmacy/weight-loss/phentermine-prozac-for-weight-.html> (Checked September 2004).

¹⁶ Muhammad Walji, MS; Smitha Sagaram, MBBS, MS; Deepak Sagaram, MBBS; Funda Meric-Bernstam, MD; Craig Johnson, PhD; Nadeem Q Mirza2, MD; Elmer V Bernstam, MD, "Efficacy of Quality Criteria to Identify Potentially Harmful Information: A Cross-sectional Survey of Complementary and Alternative Medicine Web Sites", *Journal of Medical Internet Research* 2004;6(2):e21 - <http://www.jmir.org/2004/2/e21/> (Checked September 2004). See also Morag Mckinnon, "a dose of good advice works best", *Evening News*, Edinburgh, 31st March 2003.

The Restrictions Are Already Substantially Lifted

Citizens of the English-speaking countries of the European Union have an advantage here, as do the Spanish and to some extent the French. The First Amendment to the American Constitution gives some protection to commercial freedom of speech, and this has been used since 1997 by American pharmaceutical companies to give full information to the public. Because of the Canadian and Hispanic markets, this is often reproduced in French and Spanish.

For this reason, there is already a wealth of information about medicines to everyone in the European Union with the appropriate language skills. This cannot be reversed. It is not technically possible – and may be illegal under national and international laws to try – to block access to whole classes of websites. But the several hundred million European Union citizens who do not have these languages or who are not adept at the internet, often elderly Europeans who may not be as schooled in internet use, are denied the benefits of such information.

Our proposal simply extends to all European Union citizens a right already possessed by some. And it extends that right still further to those who have it. After all, while most pharmaceutical products are available in all developed markets, they are not always available under the same proprietary name. Take this list of differences:

British Name	American Name
Glibenclamide	Glyburide
Isoprenaline	Isoproterenol
Moricizine	Moricizine
Orciprenaline	Metaproterenol
Paracetamol	Acetaminophen
Pethidine	Meperidine
Rifampicin	Rifampin
Salbutamol	Albuterol
Torsemide	Torsemide ¹⁷

It would be useful if general practitioners and patients could understand each other in the conversations already taking place in Britain. Allowing pharmaceutical companies to give information to the British market about their products would save both time and possible mis-prescription.

Full Information Is a Human Right

One of the most powerful objections to this proposal is from the various state healthcare systems within Europe. These are all under financial pressure, and are trying to contain their costs. It is feared that the pharmaceutical companies would use any right of providing information on their products to further encourage patients to demand expensive treatments they might not otherwise have known about.

¹⁷ Jeffrey K Aronson, "Where name and image meet—the argument for adrenaline", *British Medical Journal*, 19th February 2000 - http://www.findarticles.com/p/articles/mi_m0999/is_7233_320/ai_60114757 (Checked September 2004)

Health Action International (HAI) is an influential network of consumer, health, development action and other public-interest groups. It opposes liberalisation of pharmaceutical advertising partly on the grounds that in the United States, pharmaceutical costs have risen sharply in recent years because patients have made demands that physicians cannot resist.¹⁸

Again, in January 2000, a seminar was organised by HAI and funded by the Dag Hammarskjöld Foundation and the Netherlands Ministry of Health, Welfare and Sport. At the seminar, Leon Wever, Director of Pharmaceutical Affairs and Medical Technology at the Netherlands Ministry, stated:

Experience in the US has shown us that increasing direct-to-consumer advertising leads to increasing drug use and higher healthcare costs. The US has also shown us that patients are easy to influence through direct-to-consumer advertising while they are not the ones who make buying decisions or ultimately pay most of the bill. They also may not know the risk involved in the prescription of medically unjustified therapy.¹⁹

Even if not false, this is a bad objection. The citizens of a democracy surely have the right to know about products that might save or at least improve their lives. They must have the right of full access to information about their health, medical conditions and the availability of treatments.

Moreover, this right may soon be actionable. Article 11 of the Charter of Fundamental Rights, published by the European Union in 2002, proclaims that

Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers.²⁰

If state healthcare systems do not want to provide such products, patients should at least be given the chance to know about them and to arrange for alternative finance.

But, of course, state healthcare systems should not try as a matter of policy to provide citizens with a second rate system of healthcare. Let us look at the human consequences of such a policy. Take an elderly citizen of the Slovak Republic, now in the European Union – call him “T”. In April 2002, he was diagnosed with skin cancer. He had an operation to remove the tumour and seemed to have been cured. In February 2004, he was told that he had secondary deposits in his lungs and an operation was recommended to remove these. The operation failed to remove all the deposits and he was sent home in severe post-operative pain combined with arthritic pain brought on by an extended stay in bed.

To treat this pain, his doctors prescribed a drug that a search of the Internet showed to contain small amounts of aspirin. His English friends supplied him with Co-Dydramol, which is a combination of paracetamol and codeine prescribed in the United Kingdom for the relief of mild to moderate pain. For the next few months, he took this as required. It worked to control

¹⁸ *Providing Prescription Medicine Information To Consumers: Is There A Role For Direct-To-Consumer Promotion?*, Symposium Report, Health Action International Europe, 2002 - http://www.haiweb.org/campaign/DTCA/2002_symposium_report.doc (Checked September 2004)

¹⁹ Quoted from *DTCA Symposium Report*, HAI Europe, 2002, and given in “Should Pharmaceutical Companies Provide the Public with More Information on Prescription Medicines?”, a PatientView Report, June 2002, p.19

²⁰ http://www.europarl.eu.int/charter/pdf/text_en.pdf (Checked September 2004)

first the post-operative pain and then whenever the arthritic pain became a burden. In August 2004, he was admitted to hospital with deposits in his brain. He was sent home after three weeks in hospital where he received radium therapy to shrink the tumours. A further stay in bed caused severe muscle loss and greatly worsened the arthritic pain.

To treat this, the doctors prescribed inadequate doses of Ibuprofen. A further search of the Internet suggested that an artificial opiate called Tramal, manufactured in Germany, might help. After much nagging, the Slovak doctors prescribed small doses of this. It is only because his friends and relatives had access to the Internet that this poor man is now in relative comfort.

Almost certainly, the Slovak doctors have been slow to prescribe adequate pain relief because of financial constraints. Because he is retired and will not contribute again to public finances, there is no positive economic consequence flowing from his being relieved from pain in what are almost certainly his last days.

But we ought surely be looking not only at financial consequences. The relief of pain is a primary good; and the more access people have to knowledge about the best therapies available is itself to be regarded as a good in itself. If the Slovak healthcare system is short of money, there are always administrative and other reforms to be made. Financial pressure should never be an excuse for leaving people in pain that can be so easily relieved.

Full Information Develops Character

One of the general arguments in favour of any liberty is that it develops character. Even when the “Gentleman in Whitehall” really does know what is best for the people, it is a good idea so far as possible to leave the people to do for themselves. As John Stuart Mill says:

In many cases, though individuals may not do the particular thing so well, on the average, as the officers of government, it is nevertheless desirable that it should be done by them, rather than by the government, as a means to their own mental education—a mode of strengthening their active faculties, exercising their judgment, and giving them a familiar knowledge of the subjects with which they are thus left to deal.²¹

We can see this in the case of medical information from an unlikely source – from *The New Statesman*:

Tim Besley, who has spent much of his life in the US, recalls that when he first arrived there, he was bewildered by the idea of choosing healthcare. "I had become an ignorant consumer of healthcare precisely because I had been brought up in a system where choice was not available." Most Americans with a similar educational background were highly in-formed about the choices they had to take. "If you offer people choices, they will often go and acquire the necessary information to do so," he believes. In other words, choice may make people more responsible for the consequences of their actions. It may be a way to develop personal and political maturity.²²

²¹ John Stuart Mill, *Essay On Liberty* (1859), Chapter 5, “Applications” - <http://www.bartleby.com/130/5.html> (Checked September 2004)

²² Frances Cairncross, “The Curse of the Chinese Menu”, *The New Statesman*, 24th July 2000
http://www.newstatesman.com/site.php3?newTemplate=NSArticle_NS&newTop=Section%3A+Front+Page&newDisplayURN=200007240020 (Checked September 2004)

Full Information Saves medical Professionals from Temptation to be Corrupt

In February 2003, an Italian heart surgeon was arrested on suspicion that he had taken thousands of euros in bribes to buy Brazilian-made valves that investigators said might have caused the deaths of 20 transplant patients. The previous week a British pharmaceutical company was accused of offering 3,000 Italian physicians inducements to use more of its products. Italian prosecutors said the company had showered doctors with free gadgets, apparatus and cash, as well as "medical tours", including one to Monte Carlo which coincided with a Formula One event in the principality.²³

The inducements were allegedly offered because of the monopoly that physicians have on information about drugs. In America and New Zealand, pharmaceutical firms can advertise. Such scandals are almost unknown. In Europe, where direct-to-consumer advertising is prohibited, we have found one scandal; and a little more research would doubtless find others.

5. Full Information Cuts Costs (a)

In fact, however, the cost objection may be a false objection. In Britain at least, one of the most notorious misuses of the healthcare budget is on visits to general practitioners by people who have nothing wrong with them. They turn up, demand a consultation, and expect to go away with prescriptions that may be dispensed at heavily subsidised prices. The availability of full information may eventually reduce this waste of medical time and money.

Take, for example, this anecdotal case involving a person – call him G – known to the authors of this paper. Several years ago, G lost weight. One day, his wife noticed a lump at the base of his sternum. Knowing nothing of such things, they agreed it might be bone cancer. Instead of running straight to his general practitioner, though, and demanding x-rays and specialist consultations, G looked up the symptoms of bone cancer on the Internet, and realised that he had none of the symptoms. He then noticed a similar lump on the chest of a statue taken from the pediment of a Greek temple. After carefully inspecting the chests of young men in swimming pool changing rooms, he decided there was nothing wrong with him. At last, he was sent by his insurance company for a routine medical inspection. The examining physician casually noted that G was slightly pigeon-chested!

This is not a directly applicable case, as G did not look on the web site of a pharmaceutical company for the information that kept him from wasting the resources of the National Health Service. But it does illustrate the way in which individuals are increasingly taking an active and informed interest in their own healthcare – and how the impact of this may be to save money.

Full Information Cuts Costs (b)

We have suggested that giving individuals full access to pharmaceutical information might keep them entirely from visiting their physicians. It could also reduce time spent on those visits still made. Physicians do not know everything. They cannot always make instant diagnoses and give instant advice. They must often think, and sometimes even consult

²³ Sandra O'Connell, "Light shines on the medicine chest", *The Sunday Times*, London, 23rd February 2003.

colleagues of printed material. When a patient arrives with a suggested diagnosis already printed from the Internet, and a suggested course of treatment, this may be wrong – but it may also be right. A physician will often spend less time examining a human patient than a vet will examining an animal. For the same reason, a physician may spend less time examining an informed than an uninformed patient.

An Attempted Quantification of Cost Savings

It is never possible to say in advance what will be the financial effects of a change such as the one suggested. But, this reservation made, let us consider what may reasonably be estimated.

According to the Office of Health Economics, general practitioners in the United Kingdom carried out 261 million consultations in 2002.²⁴ Of these, 97 million were made by people in the 16-44 age group.²⁵ In 1997, according to a British Government Report, the average length of a consultation was 9.36 minutes, having risen from 8.33 minutes in 1990.²⁶ No figures are available for any year later than 1997. In 2000, the average cost of a consultation – excluding prescription costs – was £10.55.²⁷

These are figures from different years, and calculating from them is unlikely to produce precisely accurate results. Nevertheless, they are figures from within a five year period, during which there was low inflation, and little change in the size and structure of the population. Useful information can, therefore, be extracted – so long as the limitations are kept in mind.

This being so, let us assume that ten per cent of people in the 16-44 age group who consult their general practitioner were to research their possible ailments and the appropriate treatment on the Internet. Let us assume that their gathering of information shortens each resulting consultation by one minute. It is, after all, reasonable to suppose that discussions between a physician and an informed patient will be more focussed and therefore often shorter than would otherwise be the case. This means a saving of 97 million minutes, which makes room for another 10,363,247 consultations – or an annual saving to the National Health Service of £109,332,255.85. Against this saving must be set a potential increase in the number and therefore cost of pharmaceutical products dispensed. On the other hand, this might be partly or wholly – or more than – balanced by a saving in inappropriate prescriptions. There might well be further savings in the long term, so far as correct prescribing at an early stage of an ailment might save on more costly treatments later on. Because these possibilities cannot possibly be quantified, we shall assume that the net effect on prescription costs will be neutral.

Perhaps these very moderate estimates are in fact exaggerated. Let us, then, assume that only one per cent of people in the relevant age group use the Internet to research their ailments. This still means a saving of more than £10 million per year.

Britain is only one member state of the European Union, with around one seventh of its total population. Because there are large disparities in gross domestic product per head, and

²⁴ Office of Health Economics. *Compendium of Health Statistics, 15th Edition 2003/04*. Office of Health Economics, London, 2004.

²⁵ *Ibid.* London:

²⁶ *Review Body on Doctors' and Dentists' Remuneration, 27th Report 1998*, The Stationery Office, 1998.

²⁷ Source: news article, "NHS helpline 'more hindrance than help'", *The Daily Mail*, London 14th July 2000.

because of wide differences in healthcare provision, it is not easy to extrapolate these figures to the European Union as a whole. But let us suppose that we multiply the larger figure by three – this gives us a potential saving across the whole European Union of more than £437 million Euros in healthcare costs.

The people Want Full Information

The European Union is a confederation of democracies or it is nothing. As has been repeatedly said throughout this paper, people throughout Europe are spontaneously taking advantage of the information already available to become informed consumers of health care. But there is evidence that they want still fuller access to information.

In May 2002, PatientView conducted a survey throughout the European Union into attitudes towards liberalisation of pharmaceutical advertising.²⁸ Rather than individuals, patient organisations were approached. These represented between six and 15 million patients throughout the European Union. The question asked was “Should the European Commission legislate to allow pharmaceutical companies to supply the public with significantly more information about prescription medicines?”

The results of the survey are as follows:

Yes	33 per cent
Yes, but with strict limitations	17 per cent
The EU should study the matter further	25 per cent
Possibly/it depends	16 per cent
No	9 per cent

These were the results through the European Union as a whole. It can be seen that the largest single bloc of answers was a flat “yes”. Adding in those broadly in favour brings the “yes” response to half. 41 per cent of respondents were not sure one way or the other. Only nine per cent of respondents were opposed.

Too much can be read into the results of a single survey – especially of one that samples opinion indirectly, from organisations of patients rather from patients themselves. Even so, the results appear to support the general belief that people want fuller access to information about pharmaceutical products, and that many of them are already seeking it. So far as anything can be said about European public opinion, it seems to be that the people want much greater freedom of patient information.

Conclusion

There is no doubt that this freedom is coming to Europe. It already has for those who are competent in English, French or Spanish. All that can be doubted is when it will be officially allowed and with what limitations.

With this in mind, we strongly urge the European Union authorities to act sooner rather than later, and to be as liberal as possible from the beginning.

²⁸ “Should Pharmaceutical Companies Provide the Public with More Information on Prescription Medicines?”, a PatientView Report, June 2002