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Direct to Patient Communication:

Patient Empowerment or NHS Burden?

Edited by Jessica Asato

SOCIAL MARKET FOUNDATION
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INTRODUCTION

Jessica Asato

Much of the current drive in healthcare policy focuses on the twin goals of opening up choice for patients and encouraging them to take greater control of their health through self-care. The expansion of patient choice into the acute sector, started by Alan Milburn as Health Secretary in 2003, is a fundamental part of the Government's ambition to create a patient-centred NHS. By transferring the power to choose what is best for patients from health professionals to the individual, the Government hopes to keep up with rising patient expectations of the NHS and to drive up standards. Meanwhile schemes such as the Expert Patient Programme¹, NHS Direct, and minor illness schemes which encourage patients to seek help from their community pharmacist before approaching their GP, all indicate a recognition by Government that better health outcomes are generated when patients are entrusted with responsibility for their own healthcare.

It is in this context that the debate about whether pharmaceutical companies should be allowed to communicate directly with patients becomes significant. As the law stands in Europe, pharmaceutical companies are unable to advertise prescription only medicines (PoM) or give out information regarding those products to enquirers on request. Companies are prevented from putting information about their products on their websites, and from advertising products directly to the public through print or broadcast media. Anyone who wishes to know more about a prescription medicine is required to seek that information through a qualified medical professional.

As part of a drive to open up access to health information for European consumers and to improve the competitiveness of the pharmaceutical industry, the European Commission (EC) put forward draft proposals to change the law in July 2001. This would have enabled companies to provide information about their products directly to patients in three pilot disease areas: asthma, diabetes

and HIV, for a trial period of five years. All information provided by companies would be subject to prior approval by the European Medicines Evaluation Agency. It was unclear from the proposals whether the EC was proposing the introduction of direct to consumer advertising of prescription only medicines (PoM DTCA) as is the case in the US and New Zealand, or whether the proposals would simply enable patients to gain access to information from companies if they were to approach them. This initial confusion has clouded the debate ever since and may have led to the rejection of the EC's proposals by the European Parliament which gave the Commission three years to come back with a reworked alternative.

Whether pharmaceutical companies should be permitted to communicate with patients remains a live issue, and this collection of essays reflects different perspectives on that question. Advocates of relaxing the laws on patient communication argue that enabling pharmaceutical companies to communicate directly with patients opens up another source of information and thereby facilitates greater choice. They suggest it also empowers patients to take more control of their own healthcare, preventing their reliance on healthcare professionals for information. Many of our contributors argue, in an age when people are less deferential and more demanding of public services, those who wish to prevent the public receiving information about their potential healthcare options are fighting against the tide of public opinion.

Evidence for public hunger for more information about healthcare is clear from the fact that health-related subjects are at the top of the list of most searched for items on the internet. It is important, however, that consumers receive factually correct information in the context of their national healthcare system. Supporters of direct to patient communication suggest that excluding pharmaceutical companies from the provision of information about their products when they are in a strong position to know most about those products is disadvantageous for the consumer. They argue that not only does the status quo limit a consumer's right to have free access to information, it also runs the risk of a consumer acting upon faulty information which cannot be verified elsewhere on the internet or in the public domain without recourse to a health professional.

This dominance of information about prescription medicines and treatments by established provider interests is harmful to individuals who wish to take more control of their health needs, and also works against the model that the UK Government is pushing forward whereby health professionals act

more as patient advisers than gatekeepers of information. In the first essay, Professor David Colin-Thome sets out how within the NHS the doctor/patient relationship is already rapidly changing, shifting the balance of power further from the health professional and closer to the patient. Direct to patient communication, he argues, would be a welcome step forward, signalling that patients can be trusted to make the right decisions for themselves.

Professor Nick Bosanquet also argues that the old paradigms of the NHS must change if the NHS is to cope with new challenges such as the escalation of controlled serious illnesses and staff shortages. Direct to patient advertising has the potential, he claims, to motivate new groups of "survivors" to take-up new treatments and to get across health messages currently neglected by overworked NHS staff. It also has the potential knock-on effect of reducing NHS costs in the long term – as Keith Krzywicki points out, for every £1 spent on medicines, £3 is saved later on hospital costs. Professor David Taylor argues that some studies show that drugs advertising can get messages across to poorer sections of society who are least likely to seek medical help and have less access to other sources of information such as the internet.

A theme to which contributors to this collection constantly return is the need to champion the interests of the individual against the power of professional vested interests, whether they be the state or the medical profession. In his essay, Dr Tim Evans writes about the historical protectionism of the medical elite and the continuing barrier it presents to freedom of information, despite the obvious shift from patients accepting their lot as passive recipients of state healthcare to active consumers of healthcare. Angela Coulter, who argues in her essay against the idea of direct to patient communication, agrees that there is some merit in the charge of paternalism in this context. She contends, however, that this should not automatically lead to the conclusion that the pharmaceutical industry should be given more power to provide information to patients, because it too has a vested interest.

Those who oppose the idea of allowing the pharmaceutical industry to provide information to patients believe that it is the first step towards direct to consumer advertising which must be avoided at all costs. Pharmaceutical companies, they argue, only prioritise the advertising of those drugs which are most profitable, rather than ones which might reflect public health priorities. In particular there is some evidence to suggest that the drugs they promote may lead to the 'medicalisation' of normal human experience², convincing people that conditions such as baldness, for example, are medical problems,

making them into healthy hypochondriacs. Concern is expressed too about the difficulty in conveying information about the side-effects of particular drugs through advertisements, with evidence from a number of studies which show that the public in the US are often confused rather than informed by advertisements.³ There is also a fear that introducing direct to consumer advertising would put huge pressure on the NHS drugs bill as more patients demand expensive branded drugs instead of cheaper generic ones.

Angela Coulter's alternative suggestion to improve the information about medicines and treatments available to the public is to establish a public-private partnership which would act as an independent central gateway for patients in Europe to access medical information. All lobby groups, including the industry, would have the opportunity to provide information as long as it conformed to recognised standards of quality. This would relax the grip of the medical profession on health information, and prevent pharmaceutical companies from skewing health priorities while also relaxing the current restrictions on provision of information by the industry. This would appear to be a practical step forward in the debate about patient communication and a possible compromise in an area which has been characterised by mistrust and misunderstanding on both sides. What is evident, however, is that public demand for more information about healthcare will continue to grow and all parties involved in this issue must find a solution which puts the patient at the centre of decision-making about their healthcare. This collection of essays seeks to inform that process.

¹ The DH expert patient programme – www.doh.gov.uk/cmo/progress/expertpatient/index.htm

² Mintzes B (2002). For and against: Direct to Consumer Advertising is Medicalising Normal Human Experience. *British Medical Journal*, 324: 908-909

³ Kaiser Family Foundation. Understanding the effects of direct-to-consumer prescription drug advertising. November. 2001. Menlo Park, California, The Henry J. Kaiser Family Foundation.

EMPOWERING PATIENTS THROUGH ACCESS TO INFORMATION

PROFESSOR DAVID COLIN-THOME

"Trust me; I'm a pharmaceutical marketing expert." Does that have the right ring to it? Maybe not, but in many ways it captures the essence of the current debate on whether pharmaceutical companies should be allowed to provide information about their drugs direct to patients.

It's a development which hasn't yet hit these shores and isn't imminent given the recent rejection by EU health ministers of proposals to allow drug manufacturers to use websites and specialist publications to communicate directly with just three patient groups – AIDS, diabetes and asthma sufferers.

Glad to see the back of the proposal, consumer groups argue that it isn't the job of drug companies to supply information to patients. That's a role, says the Consumers' Association, for one central, independent and impartial body. Information provided by this body should be supplemented by medicines education as part of the national curriculum and by strengthening the communications skills of health professionals.

The proposal, first put forward by the European Commission three years ago, was to target these three patient groups and allow the industry to provide straightforward information rather than full-blown advertising campaigns. For those fearful of letting drug companies loose on the public and patients, however, this looks suspiciously like the thin end of the wedge, the thick end no doubt leading to the celebrity endorsements of drugs which is already happening in the USA.

The only other country where direct marketing of drugs is a reality is New Zealand. But the future of direct advertising is now in question there, with moves afoot to secure a ban on the practice altogether. Many of the country's GPs are adding their voices to the ban lobby, saying the content of some ads is misleading and puts unwelcome pressure on them to prescribe advertised

brands. According to the *British Medical Journal*⁴ a certain brand of asthma inhaler became a 'must have' for many patients after a TV advertisement – with patients insisting on it whether their GP felt it was right for them or not. It cost the country an estimated £0.94 million to switch people to the new inhaler between April 2002 and January 2003.

So should the pharmaceutical industry be let loose on patients? For a long time, my view was no. But, along with many other GPs and clinicians, I have made a gradual but significant shift away from the culture where patients are wholly dependent on us, the clinical professionals. Are drug companies – or at least their marketing arms – the wolf in grandma's bed? Perhaps more importantly, does this mean we view the patient as Little Red Riding Hoods, wide-eyed, gullible and about to be eaten alive? The answer in the modern NHS has to be no.

As Angela Coulter points out in her report: *The Autonomous Patient – ending paternalism in medical care*⁵, of the 198 recommendations made by Professor Ian Kennedy's inquiry team following excessive deaths among children undergoing heart surgery at the Bristol Royal Infirmary in the 80s and early 90s, many called for the need to involve patients and carers in decisions, seek and listen to their views and keep them informed.

The NHS Plan⁶ itself is a blueprint for patient-centredness and all this brings with it in terms of redefining the patient's role and rights. A modern NHS can no longer see patients as passive victims of illness – they are consumers, taxpayers and active citizens; they have the right to make decisions; the right to make choices; and, underpinning all of this, the right to information.

One key strand of NHS modernisation is shifting the balance of power away from Whitehall and the Department of Health towards primary care trusts – the frontline commissioners and providers closest to the communities and individuals they serve. But devolution can't stop there or the newly empowered organisations become the new centralists. Devolution must now be about passing more control of services to the clinician and empowering the patient. An empowered patient is one with access to reliable information; choice; a voice; and, where they request it, control of their care.

Considering that for so long the balance of information has been severely distorted towards clinicians, it's tempting to view direct to patient communications from the pharmaceutical industry as a positive, if bold, experiment in redressing the long-standing imbalance.

The Red Riding Hood analogy is obviously extreme, but what are we really saying by holding information back from patients – information which, as clinicians, we can access freely? Are we saying the patient can't handle it – they might be swayed by the big sell? Drug companies have been advertising to the clinical market for decades – many patients are sure to feel the indirect effects of these campaigns through the prescription choices their GP, hospital consultant or nurse makes.

Add to this the fact that some drugs and much information are already available on the internet, and isn't the genie already out the bottle? Perhaps the imperative now is less about trying to tighten up who has access to information, and more about creating an environment of plurality of information and genuine partnership between patient and clinician. But, as the current debate in New Zealand demonstrates, the pharmaceutical industry must shoulder a significant part of the responsibility in providing better and balanced information – not least to clinicians.

The transition towards an enhanced partnership between patient and clinician, where the patient is the 'co-producer' of their health care, will no doubt be easier for some than others. But the transition will need to be made if self-care and collaborative care – and all the benefits these will bring for patients, carers and the NHS – are to be brought into the mainstream as serious and sustainable aspects of modern health provision.

Most care – around 80 per cent – is definable as self-care, whether for acute conditions or chronic diseases like diabetes and heart failure.

Given that between 100 million and 150 million GP consultations a year are for potentially self-treatable conditions⁷, no-one can afford to ignore the power of an informed patient, confident about self-care. And the basis on which to build is surely the public's own appetite for greater control over their health. Over-the-counter medicine sales are totalling about £1,762 million a year in Britain⁸; NHS Direct has handled more than 22 million calls between 1998 and 2004⁹; two thirds of internet users have researched health issues online¹⁰; and sales of consumer health magazines have grown at around 20 per cent a year in the last decade¹¹.

The evidence base for self-care is growing too. Robust research studies have provided examples of the benefits of generic self-care measures. Visits to GPs can reduce by more than 40 per cent;¹² hospital admissions can drop by half¹³; and outpatient visits can be reduced by 17 per cent.¹⁴

Nevertheless, internationally, self-care has traditionally lacked status. It has

been something of a cottage industry and certainly is no major player in the current culture of health care. It is a situation which is already changing on the other side of the Atlantic. In the USA, for instance, health care provider Kaiser Permanente has a vigorous programme in place to strengthen self-care, self-management and shared decision-making practices.

Here, the NHS Plan reforms have laid some valuable foundations in building a culture of robust patient information and support. The 'patient prospectus' for instance is now sent out to all households by primary care trusts giving information on local services. Patient feedback, through local patient surveys, now informs a trust's star rating – a major driver given that one of the most common frustrations expressed by patients is lack of information about their condition or treatment. Moreover, assessment of patient experience forms an integral part of the quality framework introduced with the new contracts in primary care.

Helping people to self-treat for minor ailments is also crucial. The NHS has not always handled this aspect of self-care very well. One study found that GPs spend 39 per cent of their time dealing with minor ailments, and another that each GP's workload could be reduced by 16 consultations a day if self-medication was used for certain minor conditions.

For many patients too, it's an irritating inconvenience to have to resort to their GP for less serious illness such as coughs, sore throats, hay fever and dyspepsia. Giving a stronger, more visible role to community pharmacists is one avenue which the NHS is seriously exploring¹⁵. There are now more than a dozen successful schemes which have established a systematic referral process from the GP to the pharmacist for specified minor conditions and there's scope to extend this approach across the country.

NHS Direct and NHS Direct Online are already integral information tools in the self-care pathway for minor ailments – with NHS Direct Online taking thousands of hits a day. The role of more interactive media is being piloted in the USA. One trial led by US academic Jack Wennberg¹⁶ showed that out of a group of men listed for prostate surgery, 50 per cent decided against the operation once they'd worked through an interactive computer package giving them more information about the condition and its treatment.

While web-based information and interactivity may be a significant growth area for the NHS in terms of patient information, it could serve to widen social exclusion, disenfranchising those unlikely to use or access online facilities. The Department of Health has already recognised the potential of digital television

technology in bridging this gap. A recent pilot scheme brought NHS Direct services into 50,000 homes in Birmingham through their TV screens and the Government has agreed to further developments in this area.

For patients with chronic illness, such as asthma, arthritis, diabetes and heart failure, another valid source of information and advice is other sufferers. The Department is actively supporting an "expert patient" programme¹⁷ where fellow sufferers are trained to help patients with chronic illnesses to manage their disease in the long term. A study by Professor Kate Lorig, the American founder and pioneer of the Chronic Disease Self-Management Course (CDSMC) at Stanford University,¹⁸ showed that this approach not only helped arthritis sufferers improve their quality of life and feel more in control of their condition, but also helped reduce demand for clinical services.

Two waves of pilot programmes to train expert patients are currently taking place in this country, with around 20,000 patients receiving training in this pilot phase.

Just looking at diabetes, it is easy to see the potential benefits of more information and self-management support for those with chronic conditions. It's estimated that a diabetes sufferer spends just three hours a year with clinicians, and, as a group, only 50 per cent of people with diabetes take their medication properly.

In fact, despite the reality that medication is the most effective intervention for chronic disease, 50 per cent of medicines for all long-term illnesses aren't taken as intended. The Medicines Partnership Task Force¹⁹ is an initiative supported by the Department of Health to help patients achieve the maximum benefit from their medication. It brings into play the idea of 'concordance' rather than compliance. The patient and clinician work as partners to reach an agreement about the illness and the treatment – an agreement which takes full account of the experiences, beliefs and wishes of the patient.

There has been a lot of discussion about the vision of collaborative care and an equal partnership between the health professional and the patient. For a long time the only thing patients were expected to bring to the table was their illness – that is clearly changing. But the risk is we still underestimate the patient's contribution: "I'll bring the clinical expertise; you bring the knowledge of your symptoms, lifestyle and family circumstances". Yet for many chronically ill patients, this is to ignore the considerable technical expertise they often build up about their condition. If patients are hungry for information, we should feed, not starve them.

In 1871, Dr Oliver Wendell Holmes told his medical students: "Your patient has no more right to all the truth you know than he has to all the medicines in your saddlebags. He should get only just so much as is good for him."

How much information is good for a patient? It's time to let them decide.

The views expressed here are the personal opinions of Professor Colin-Thome and do not necessarily reflect those of the Department of Health or any other organisation for whom he works.

⁴ *The British Medical Journal* No 7402 14 June 2003.

⁵ Angela Coulter (2002) *The Autonomous patient – ending paternalism in medical care* (The Nuffield Trust – published by The Stationery Office).

⁶ The NHS Plan: a plan for investment, a plan for reform. Department of Health 2000, CM 4818-1.

⁷ Editorial (1994) *Over-the-counter drugs*, *Lancet* 343: 1374-5.

⁸ PAGB Annual Report 2002-2003.

⁹ NHS Direct Department of Health statistics (from the launch of NHS Direct in 1998 to February 2004). By 2006 it is estimated that NHS Direct will handle 16 million calls per year: *Developing NHS Direct: A strategy for the next three years* DoH 2003.

¹⁰ Dr June Raine, MHRA presentation to the AESGP members meeting "New legislation – new opportunities?" How to mutually recognise an innovative non-prescription medicine. January 22nd/23rd 2004.

¹¹ *ibid.*

¹² Fries J et al (1998) *West J Med* 169: 201-207.

¹³ Montgomery et al (1994) *The American Journal of Medicine* Vol 97: 429.

¹⁴ Lorig et al (1985) *Medical care* 23, No 9: 1044-1054.

¹⁵ *Better management of minor ailments: using the pharmacist* (Royal Pharmaceutical Society of Great Britain) www.rpsgb.org.uk

¹⁶ Flood, A.B., Wennberg, J.F., Nease, R.J.F et al. *Journal Gen Intern Med* 1996, 11, 342-9.

¹⁷ The DH expert patient programme – www.doh.gov.uk/cmo/progress/expertpatient/index.htm

¹⁸ Stanford University Arthritis Self Management Programme <http://patienteducation.stanford.edu/programs/asmp.html>

¹⁹ The Medicines Partnership www.medicines-partnership.org

DIRECT TO CONSUMER ADVERTISING OF PRESCRIPTION MEDICINES IN EUROPE: ITS PLACE IN INFORMING THE USE OF PHARMACEUTICALS

DAVID TAYLOR

Direct to consumer advertising of prescription only medicines (PoM DTCA) is a highly controversial issue in Britain. Against the background of the European Pharmaceutical Review and deliberations such as those of the 'G10 working group',²⁰ organisations such as the Association of the British Pharmaceutical Industry, the British Medical Association, the Royal Pharmaceutical Society, The Consumers' Association, Social Audit and patient groups such as the Multiple Sclerosis Society have put forward conflicting opinions about its potential value and drawbacks.

Many influential bodies are strongly against the introduction of PoM DTCA in this country and abroad.²¹ Yet there is little compelling evidence that it would radically change patterns of medicinal drug use, or – especially given European pharmaceutical price, purchasing and prescribing controls – health care costs.

Even in the United States (where there is no equivalent to the UK's P medicine classification, which allows all over the counter medicines to be advertised although some can be supplied only by a pharmacist) direct to consumer medicine advertising accounts for about 2 per cent of all pharmaceutical expenditure. The DTCA outlay there is some \$3 billion, out of a total US pharmaceutical marketing budget of circa \$20 billion.²² Total medicine costs in the US remain lower as a proportion of overall health costs than is the case for the European Union as a whole, and that of individual countries such as the UK. Whatever the reasons for America's high health spending or poor health standards amongst some minority groups, such problems cannot coherently be attributed to direct to consumer advertising of prescription medicines.

There is according to the US Food and Drug Administration (FDA) (which is arguably the world's most competent medicines regulator) little or no evidence that PoM DTCA has caused significant harm in the US since the liberalisation of controls there in 1997. There are, however, also limited indications of public benefit. People on long term medication programmes appear to value PoM DTCA (albeit that many educated, healthy, adults dislike it) and are on occasions prompted to remember to take their drugs. There is evidence that such promotion leads a proportion of individuals with health concerns to request treatments, and that in a proportion of such instances clinicians prescribe accordingly. This has been decried by some commentators,²³ but it should not automatically be assumed to be undesirable, any more than it necessarily implies better care.

A similar situation appears to exist in New Zealand, the only other developed economy which currently permits this form of promotion. Its critics claim that DTCA of prescription drugs puts pressure on 'the doctor/patient relationship', may mislead patients and, from their perspective, wastes health resources.²⁴ But there is nevertheless little firm evidence of substantive harm, and counter-balancing arguments exist in favour of honest, appropriately regulated, commercial communication about medicines and all other goods and services.²⁵

So why is the PoM DTCA issue so contentious? The answers in part relate to its implications for the empowerment of health service users, and the ways it impinges upon the vested interests of a variety of powerful groups. In Europe the latter include, in addition to the advertising industry and the rival branches of the state and privately owned media, the following:

- **the health professions.** The position of doctors and other health professionals is determined by their control of, and access to, information about health related goods and services. Interference with the 'doctor/patient relationship' may be seen as action which threatens the economic interests of the medical profession,²⁶ which has the capacity to mount strong retaliatory attacks in Europe;
- **national governments.** All governments in Europe seek to manage patterns of health care demand and supply, and gain political advantage from this;
- **the European Commission.** The Commission aspires to become the recognised champion of European public health

improvement, and a popularly accepted judge of the quality of health care delivered by member state governments to European citizens resident within their localities;

- **the pharmaceutical industry.** National and international companies exist to profit from selling medicines in the EU, and other markets. Groups such as Health Action International,²⁷ Social Audit and The Consumers' Association wish to limit their freedom to do so. They might also want to see alternative systems for funding pharmaceutical research and development.

This brief paper outlines evidence relating to the European PoM DTCA in these contexts.

From professional control to consumer sovereignty in health care

The ongoing transition from a historical situation in which professionally qualified people such as doctors and pharmacists were part of a small, very secure, knowledge – and skills-based workforce elite to one in which they are required to serve their customers as equals is naturally a painful one.²⁸ As noted above, it threatens their social standing, and their relative incomes. Seen from this perspective, new information sources like the internet may bring with them not only the advantage of service users who are more questioning, and therefore capable of contributing to their care,²⁹ they can also make the processes of treatment selection and 'patient instruction' more complex, challenging and time consuming.

Although many UK practitioners welcome such progress³⁰ their representatives are aware that it is resented by others in the profession. This helps to make PoM DTCA a matter of powerful symbolic significance in health sector politics. Further, the overtly commercial motives underpinning advertising in the health arena may, by association, undermine professional self images which, despite the reality of their above-average financial earnings, have been based on a popular belief that senior health workers are more 'ethically' motivated than most of those they serve.

The term 'partnership in health care' has been used by change advocates to moderate concerns about the impact of greater professional accountability to service users, and facilitate recognition of the need to respect patient autonomy.³¹ Such strategies (and consequent sensitivities towards the use of more assertive language such as consumer sovereignty in health care) might in

part explain why on occasions such individuals have appeared to adopt belief as opposed to evidence based positions about the undesirability of PoM DTCA. Some commentators who have been invited to play key roles in representing consumer views to the European Commission have expressed categorical opinions that 'it will not help' and should be opposed.³² A number of patient groups in the UK do not share this view.³³ They see recently proposed European reforms as a veiled attempt to limit their ability, and that of commentators such as journalists, to provide information about medicines in an independent manner.

The processes involved in informing people about medicine taking and building relevant knowledge, beliefs and patterns of behaviour are still poorly understood by many health professionals. In Britain, for example, initiatives such as the DoH's Expert Patient Programme (EPP³⁴) have been greeted with a mixed professional response. There is compelling evidence that a major element of the value of the techniques embodied in the EPP lies in raising consumer self confidence (self efficacy) in relation to medicine taking and communicating with professionals,³⁵ rather than levels of knowledge *per se*. Yet many doctors, pharmacists and nurses seem still to see 'empowerment' as something they confer on patients, through traditional didactic interventions.

Critics of PoM DTCA sometimes appear insensitive to the fact that there are many types of useful health and medicines related information and behavioural encouragement, from the new and complex to the familiar and simple. Advertising is normally focused at the latter end of this spectrum. Research on effective medicines-taking support emphasises the need for multiple and complementary levels and routes of communication.³⁶ There is some limited evidence from both US and European sources that public advertising via television (the printed media gain less from PoM DTCA revenues) may be of particular value in bringing medicines-related options to the attention of less advantaged minority groups,³⁷ who unlike their more affluent peers have at present at least limited access to resources such as the internet.

National governments' motivations, and the European Commission's objectives

Most governments want both to improve public health and support local industries in strategically significant sectors. Politicians also want to limit tax funded expenditures, and retain their popularity not only with the electorate as a whole but also with key stakeholder-group members positioned to

influence wider voter populations. This gives them conflicting incentives in relation to topics like investing in community as opposed to hospital-based services, and spending on medicines. In private, for instance, decision takers may view providing more effective treatments in low cost primary care settings with relative favour. But overtly they may be more inclined to emphasise the value of hospital improvements, and employing more staff.

In Europe, where concepts such as the right to free communication have had relatively little traditional support compared to the situation in the US political environment, championing the removal of controls on direct pharmaceutical company communication with the public is – however effective the regulation of such promotion – unlikely to appeal to many politicians. Similarly, the political interests of the European Commission are more likely to coincide with those of powerful professional groups than with those of research based or other pharmaceutical companies. Although the pharmaceutical industry has the potential to contribute to the European economy (and is of special importance to the UK, as well as to countries like Switzerland and America) it employs relatively few people, and has limited popularity. The health professions are by contrast numerous, and enjoy high standing.

European officials say that over coming decades they want to strengthen the role of the Commission in fields such as public health, and assuring citizens' rights to high quality care. Achieving this objective may demand considerable support from influential power groups other than member state governments. The interests of European Union authorities also lie in the direction of creating pressures to reduce locally based regulatory disparities.

In the context of pharmaceutical sector policy formation, this may help to explain why the European Union approach can seem unsympathetic to issues such as the research based pharmaceutical industry's concerns about the parallel importing and exporting of patented, branded, medicines between EU countries with different systems of medicines price regulation, or the possible benefits of deregulating some forms of medicines information provision. Building a more unified Europe may, some commentators fear, be taking priority over developing evidence-based industrial and allied health policies.

The pharmaceutical industry's dilemma, and its critics' power

In such a situation pharmaceutical companies face a number of dilemmas as to how they position themselves in relation to European and national governmental agencies, and medicine takers as opposed to their prescribers

and dispensers. In the past, for example, doctors have had more or less unchallenged power to determine patterns of medicine use. Pharmaceutical companies must still respect their skills and vital role, and meet their requirements. But at the same time they must respond to new imperatives, such as those associated – in England – with the extending role of pharmacists and prescribing advisers; the responsibilities of PCT managers; and the needs and wishes of a more educated, more affluent and older public. Doing so without alienating their more traditional customer groups is a challenging task.

At the same time the pharmaceutical industry's traditional business model is coming under heavy pressure. Rising research costs, new technical challenges and a possible future decline in high volume, low unit cost, 'block-buster' products balanced by a rise in the numbers of high unit cost, relative low volume, innovations are demanding fundamental changes in corporate structures and ways of working. Simultaneously, groups critical of the pharmaceutical industry and wider aspects of the way global society is ordered have mounted organised campaigns on topics like intellectual property protection (medicine patenting and branding), pharmaceutical pricing, and marketing practices. The PoM DTCA issue can be linked to all of these areas.

Given the complexities and risks of this situation, organisations representing the pharmaceutical industry in Europe appear have adopted a relatively conservative position with regard to the public advertising prescription medicines. While arguing that they should at least be as free as other organisations to offer – within a public interest oriented regulatory structure – medicines information via the internet, and disease management support services autonomously accessed by medicines users, they have not pressed for PoM DTCA.

This may to a degree be because of doubts about its cost effectiveness from the commercial and public health improvement perspectives. It may also be related to fears that even though duly regulated prescription medicine advertising (and/or public health education advertising about health problems and classes of treatment, as is allowed in Canada) might well be in the European public's interest, the vested interests ranged against it represent a coalition too powerful to fight. For instance, the forces allied with The Consumers' Association's position against DTCA in the UK and Europe can combine patrician medical paternalism with socialist activism, and public money with 'middle England' purchasing power.

Conclusion – towards health improvement in a free society

Questions about whether or not and in what circumstances PoM DTCA should be permitted in Europe are not of fundamental importance as compared with, say, improving poor world medicines supply and the quality of care for older individuals with disabling conditions in countries like Britain. Further, the quality and extent of the evidence available should not be thought sufficient to support categorical responses.

However, the conclusion drawn here is that it would probably be in the UK public's best interests to move to a position in which any agency concerned with the manufacture, supply or use of medicines is free to supply information about them directly to the public and, as economic incentives determine, advertise them provided that all claims made are demonstrably honest and that the political and economic benefits of freedom of communication in principle are not outweighed by robust proof of substantive harm in practice.

Such a finding may by some be regarded as indicative of bias related to personal interests and experience.³⁸ Nevertheless, it can be argued that the current situation in Europe in relation to much health policy formation often seems unduly paternalistic, and open to establishment led manipulation. Failure to investigate in an open manner how regulations seemingly designed to protect public health may in fact serve to protect concealed sectional interests could reflect an 'old European' bias against transparently regulated competition, and rigorous intellectual integrity. This in turn could inhibit future health improvement in areas such as heart disease and diabetes prevention, which will require a progressive shift of control over information about, and use of, medicine-based technologies into the normal daily lives of the educated, ageing populations of regions like modern Europe.³⁹

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²² Scrip Daily News Alert (2003). Ref: 35114. *US promotional spend for medicines doubles*.

²³ Mintzes B (2002). For and against: Direct to Consumer Advertising is Medicalising Normal Human Experience. *British Medical Journal*, 324: 908-909.

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DIRECT TO CONSUMER ADVERTISING – AN INFORMATION IMPERATIVE FOR THE NHS?

NICK BOSANQUET

The proposal for direct to consumer (DTC) advertising needs to be evaluated in relation to the specific problems faced by patients in each health system. The balance sheets for the US and the UK are likely to be very different. Within the UK the key challenge is that of building new kinds of partnership between patients and professionals at a time when patients' expectations are moving well ahead of the capacity to communicate with them. Another challenge the NHS will have to tackle is how to cope with the increasing numbers of people with controlled serious illnesses while we still face shortages of experienced staff. The potential role of DTC advertising has to be assessed with this future health service context in mind.

The first reason why DTC advertising should be considered is because the traditional "doctor knows best" model of healthcare is changing. National Service Frameworks are shifting away from the old paradigm of health care by which individual patients seek diagnosis and treatment for symptoms, towards a new paradigm by which populations are screened for high-risk individuals⁴⁰. It then becomes a professional duty to treat these individuals even if they have no overt symptoms. Some who go on to develop disease will move onto care pathways or protocols with the emphasis on early intervention and preventive action. Such pathways often stress whole person health and lifestyle change. The effect of this new paradigm is to create a much larger group of people who are in the health system over a longer period of time and for whom long term motivation and communication are much more crucial to effectiveness in care.

Simultaneously, the number of people with controlled serious illness who may face new problems in the future are increasing, creating a new group of 'survivors'. Over the last three decades the number of people with end stage renal failure has risen from a few hundred to over 30,000, indeed the numbers

have doubled in the last 10 years. Other groups of survivors include one million people in the population who have had cancer diagnoses in the past five years. The numbers will increase as numbers with lung cancer decline and cancers with higher survival rates, for example prostate and breast cancer, increase. There will be many survivors who have had serious cardiac events and the rising incidence of the malignant disease of depression is a worldwide phenomenon. Again, there will be many people facing possible recurrence.

This group of survivors is different and smaller than the group with risk factors, but they amount overall to 5 – 10 per cent of the adult population and they represent a high cost both to society and to the NHS. Survivors on renal dialysis cost £25,000 each per year and the longer term costs and recurrence risks for cancer and coronary heart disease are substantial. However, there are also positive opportunities to improve a patient's experience with successful outcomes. Although the specialist services are always going to have the main role in the treatment of this survivor group, there is considerable scope for local support programmes, monitoring of progress and lifestyle changes.

Given the professional time and skills available, the NHS is not structured in a way which will make an easy transition to this new paradigm. Direct to patient advertising, however, may have the potential to improve communication and motivation with groups helping to contribute to faster diffusion and better take up of new therapies. A study by the Kaiser Family Foundation found that after watching advertisements for drugs for asthma, cholesterol or heartburn, 40 per cent of the people who watched the ad were likely to discuss the condition with their doctor and would not have done so otherwise.⁴¹

The second factor affecting the DTC advertising debate is that the NHS now faces a situation in which the power and information available to the patient/consumer has been vastly increased. As Slywotzky and Morrison note, "There has been a secular shift in power from the supplier to the customer."⁴² From the health point of view we are only at the start. In the future customers are going to ask harder questions and demand more choice. The NHS is not going to be able to alter the speed of change of its customers' requests.

It is also going to have problems in delivering a full service because of greater funding pressures, particularly once the current three-year spending round has come to a halt. Much of that new money has already been spent and it is unlikely that such a high level of increased funding will be available in the future. Indeed the NHS may face a situation where it is above European levels

of funding but well below European levels in service. Even with enhanced funding the NHS will need to spread limited funding over services for a local population. This will make it difficult to find the additional funding needed to satisfy rapid increases in consumer expectation.

As a response to the tide of increasing consumer demands and expectations, the NHS is seeking to increase its patient focus and to offer more choice. This is going to include a long process of exploring patients' preferences and putting primary care at the frontline of developing services closer to patients. The response of producers in the NHS, however, is to concentrate services in big hospitals and to maintain the old paradigm. Patients' voices need to be strengthened if they are to have any chance of reducing the power of these traditional forces. Relaxing the rules on direct to patient advertising fits into the new model of a 'patient-centred NHS' by providing patients with the information they need to make their own choices about their healthcare. Encouraging patients to be more health literate may also help in the long-term to keep down rising NHS costs by producing better health outcomes, thereby reducing the need for expensive hospitalisation.

A third way in which the context is changing is the shortage of experienced staff, which is likely to worsen over the next five years with the high level of retirement both among GPs and among nurses. The NHS used to work with a core of experienced personnel; ward sisters in hospitals, GPs and community nurses, who got to know their patients on a personal basis and who also in many cases had a store of experience and a reserve of ingenuity which served patients well. In 1961 a survey showed that 44 per cent of patients saw their doctor as their personal friend⁴³. Now the NHS presents a picture of rapid staff turnover and heavy dependence on agency staff within the hospital service especially in London and the South East. Primary care has seen a rise in larger practices – nearly a half of GPs work in practices with five or more partners where there may be a lack of personal contact.⁴⁴

The amount of time GPs spend with a patient in an average consultation may often not be long enough to communicate all the information patients need. There is evidence to suggest that many of the complaints brought against healthcare professionals are due to a failure to provide patients with all the necessary information.⁴⁵ Over the next few years a generation of experienced staff will leave particularly in primary care and community care, and it is by no means clear how they are to be replaced. The NHS may have improved breadth in terms of speeding up of access—but it will have much

more difficulty in improving depth in terms of effective problem solving and the continuity of relationship, which some patients seek.

Direct to patient advertising forms part of a process which recognises that patients have different wants and preferences. The NHS will be able to make more effective use of the scarce resource of experienced staff time if it embraces the view that patients should be empowered to seek out their own information and take control of their own healthcare needs.

The final reason which alters the healthcare debate is that the NHS is losing support from the younger generation. The NHS has traditionally had a public opinion bonus through the gratitude and devotion of many elderly people but up to 50 per cent of young people express dissatisfaction. This generation is on the right side of the digital divide and has a very different access to information.⁴⁶ There are already significant differences emerging in information availability with the better off having access to a great deal of US information via web sites. Restrictions on advertising simply limit access for the less well off. It helps to create an information inequity, which is one of the main sources of inequity in care. Postcode rationing is strongly related to differences in information. Even after NICE recommendations on the use of anti-Alzheimer's drugs the differences in use between affluent and other areas have increased rather than reduced.

The NHS has already created a massive new challenge in care for the next decade as well as new opportunities to deliver effective services. There is a greater recognition of what can be gained from early assessment and treatment in the initial stages of disease, and the opportunity to use a new range of effective drug therapies. Earlier treatment and better communication with patients is essential if we are to make significant reductions in major diseases. With the current range of therapies we could virtually eliminate mortality under 75 from heart disease, cancer and stroke. Indeed this has already happened in more affluent areas in the western world. In the current outlook for health services in the UK, the case for DTC advertising is a strong one. It would energize the search for partnership between patients and professionals, and help widen the opportunities for patients to take more control over their healthcare.

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DIRECT TO PATIENT COMMUNICATION; THE INDUSTRY PERSPECTIVE

Keith Krzywicki

Much of the current controversy about direct to patient communication stems from a confusion about what the pharmaceutical industry wants and what it is perceived to want. Patients, providers, government and industry all agree that there should be better access to accurate and empirical information on healthcare and medicines. The informed patient benefits from increased knowledge which improves their own health and the nation's health. How this information should be provided, however, remains the sticking point. The Informed Patient Task Force (IPTF)⁴⁷, which speaks for the pharmaceutical industry on the issue of patient communication, has argued that pharmaceutical firms could help to better inform patients if they were allowed to provide scientifically reliable information on healthcare, medicines and treatments directly to patients, something which they are unable to do at present.

This position is supported by a number of patient groups and is entirely consistent with the position of the Medicines Control Agency (which represents the Government on this issue) on the provision of health information to consumers. This is stated thus: "The UK government does not support direct to consumer advertising of prescription medicines but is supportive of the provision of information to patients." This shows that there is common ground between the regulators and the industry. At issue, however, is the way in which this information is provided.

At the moment direct to patient information does not fit well within the UK healthcare system. Although many of the IPTF's members are global firms, they all recognise that current practice in other markets (for example, the US where advertising of prescribed products is wide-spread) may not translate well to other healthcare cultures. It is an area which needs closer examination,

but at the moment the IPTF is more concerned with other methods by which to educate and inform those who need to manage their own healthcare. Here the industry's stance is clear; current limitations on the industry's ability to communicate with the public hinders responsible practice which demands that pharmaceutical companies be involved in patient empowerment.

These limitations prevent pharmaceutical companies from providing any information about therapeutic areas, conditions and treatments to the patient. This is despite disease awareness and product information development following years of research and analysis by the industry. Positioning pharmaceutical companies solely as manufacturers and suppliers is short-sighted when the industry has so much to add to health provision. With appropriate regulation, the industry's expertise could be used to help patient enquiries and develop consumer awareness.

This reference to regulation is not half-hearted. The pharmaceutical industry has always been subject to controls as is appropriate for its position as a producer of medicines and healthcare. An acceptance of third-party regulation goes hand in hand with the industry's desire for tightly-controlled mechanisms to enable accurate communication of factual information to the patient. This would be far preferable to the current situation.

The absence of UK industry voices which could provide accurate, up-to-date information on conditions has meant that patients (especially those younger generations uncomfortable with traditional doctor-patient relationships) are more and more often turning to the Internet for research purposes. Usually a powerful tool, the web becomes an unpredictable source of information in the context of healthcare. The unwitting patient can all too easily gain access to a set of guidelines to a treatment untested or discredited in their part of the world. A seemingly-familiar brand name could well differ in components, application and licensing to that medicine which is taken by the patient.

This situation is far from ideal and it is a step forward that the Medicines and Healthcare Products Regulation Agency is conducting a commission on the subject of regulating patient information on the world wide web. In the meantime however, the industry could play an important role in provider-patient relations. Many studies show that the more knowledgeable a patient is about treatment options, the better their consultation and their course of treatment progresses. Informed patients are likely to have a more meaningful dialogue with their doctor and appreciate the benefits of following their treatment regimens. They are also more able to understand the risks and

benefits of a given treatment. Informed patients are more willing to seek medical help for conditions that might otherwise go untreated, including asymptomatic diseases, based on care management pathways, for example. Disease awareness campaigns in the media have been proven to reach the less affluent, a group who we know tend to be more resistant to traditional health care services.

There are compelling reasons why both the NHS and the industry are beginning to learn to defer to the patient. We know that there is a positive correlation between awareness of medicines and life expectancy. The more patients know about their conditions and the treatments available, the more confident they will be in deciding upon healthcare options in consultation with their doctor. And if the patient is more informed about, and thus likely to continue with, their course of medicine there are undoubted economic advantages. An examination of costs will reveal that public spend on medicines is more than offset by savings in acute care later on in the patient's life. Combining NHS and social care costs, we see that for every £1 spent on medicines £3 is saved later on hospital costs. This new way of looking at public sector costs is an exciting one, and is already being enacted across some PCTs, which can allocate both health and social care resources.

Compelling social, economic and individual benefits have led to encouraging developments in the field of patient information, of which this publication is one. All contributors agree to some extent on the patient's right to have greater choice in their healthcare, and positive debate such as this will continue to help shape views as we move towards a patient-centered provider model for the 21st century.

⁴⁷ The remit of the IPTF is to work with the Association of the British Pharmaceutical Industry (ABPI) to make recommendations to the Medicines Control Agency (MCA) which is now the Medical and Healthcare Products Regulatory Agency (MHRA) on direct to patient information.

THE STATE, THE MARKET AND FREEDOM OF HEALTH INFORMATION

DR TIM EVANS

The medical profession in Britain and Europe has always been largely hostile to the notion of freedom of information for patients. It was Dr David Green who first examined the rise of such restrictive practices in his seminal book, *Working Class Patients and the Medical Establishment*.⁴⁸ Here he points out that by 1887 the British Medical Journal (BMJ) was articulating deeply anti-consumerist views in order to push through producer interests. For example, the BMJ asserted that it was: "degrading to any medical man to allow his professional knowledge to be used by a commercial company as its stock-in-trade".⁴⁹ By the dawn of the twentieth century British doctors had come to accept the protectionist view that medical advertising of any kind was itself nothing more than "infamous conduct" and in 1902 they managed to pass a resolution which outlawed its practice.

Now, at the dawn of the twenty first century, and for the first time in human history, mankind can communicate globally, in real time. Across Europe, people are richer than ever before, and they are more demanding. Today's young, in particular, are comfortable with the psychology of consumerism and the opportunities that a new world of freedom and choice is opening up to them. As the products of an increasingly globalised environment many young voters find themselves at odds with those politicians who appear to endlessly talk about such old fashioned, backward looking, and anachronistic concepts as health rationing, queues, and restrictions to new and expensive medicines.

In today's world, politicians, organised medical professionals or any other producer interest that seeks to restrict people's access to information will find it increasingly difficult to hold their ground. If they try to restrict the world of direct to patient advertising too firmly, they will find themselves increasingly marginalised and on the losing side of history.

Context and Background

It was the Japanese management theorist Kenichi Ohmae who wrote in the *The Borderless World*:

"In the past, there were inefficiencies – some purposeful, some not – in the flow of information around the world. New technologies are eliminating those inefficiencies and, with them, the opportunity for a kind of top-down information arbitrage – this is, the ability of a government to benefit itself or powerful special interests at the expense of the people by following policies that would never win their support if they had unfettered access to all relevant information."⁵⁰

In British health care, the current generation of politicians are busy trying to get themselves off the hook of past political promises. As the political class increasingly struggles to cash the cheques of previous promises to 'free, unlimited and universal health care', the government (somewhat below the radar screen of popular consciousness) is striving to introduce ever more radical, market-oriented and commodifying policies – particularly when it comes to provision.⁵¹

In British health care, the direction of travel is clear. The Private Finance Initiative, Public Private Partnerships, the 2000 Concordat with Independent Hospitals, 'earned autonomy' for NHS hospitals, Foundation Trusts and now privately run Diagnostic and Treatment Centres (no doubt with a growing number of private pay-beds), all chart a clear and systematic direction in policy.

One realises just how far Britain has travelled in health, when one considers that the declared aim of the government is that it now wants all hospitals to revert to independent not-for-profit Foundation status by 2008, which incidentally, is where most of them came from in the pre-nationalised world of the 1930s and 1940s.⁵²

The Inexorable Rise of Consumerism

Today's politicians must be made aware that the world is changing. The conjuncture of failing state services with the rise of the psychology of consumerism means that patients are no longer prepared to be the passive recipients of inadequate state health care services.

In a world away from the early NHS, there are now nearly seven million people in Britain with private medical insurance, seven million with private health cash plans and millions more who chose other private alternatives such as self-funding. In the year 2002 alone, more than a quarter of a million people chose to self-fund for independent acute hospital surgery and treatment – that is, without any insurance at all. In dentistry, more than a third of the population is treated in the private sector. And more than eight million people pay privately for a range of complimentary medical therapies. According to research published in the Daily Telegraph, it is even the case that more than 3.5 million trade unionists, over 50 per cent of the Trade Union Congress's 6.8 million membership, now enjoy the benefits of private health cash or medical insurance plans.⁵³

Overall, these trends are important because they demonstrate that, in addition to people paying their taxes towards state health care services, millions are now prepared to buy privately the additional health services that they require. Millions of people are becoming *de facto* health consumers.⁵⁴ In terms of political economy the overall trends are hugely significant. As private health services and products expand and grow in popularity so they also gain momentum in terms of electoral power. Which political party would now dare to try to outlaw or undermine private health schemes?

The conjuncture of the government's public private partnership agenda in the NHS and the broader rise of private health products are not only significant because they fundamentally change the institutional landscape of health care delivery (who owns a hospital, who delivers a service), but because they also change the incentive and opportunity structure for additional income generation (private pay-beds, charging private insurers the costs of motor accidents, etc).

Beyond Producer Interest in Europe

Just as the institutional landscape of healthcare is changing, so health information is becoming more patient-centered and responsive.

In many ways, the process in Europe is already advanced. In Sweden, Germany, Spain, and across much of Central and Eastern Europe, institutional reforms (privatisation of provision, contracting out of services), that continue to erode the old top-down structures of health delivery are underway. Educated Europeans are increasingly accessing high quality American-based web and information sites and involving themselves in the decision making

processes that concern their own health care. As the information revolution highlights the often complex and subjective choices people can make when it comes to medicine, so people's awareness and knowledge base is improving.

In a spirit of genuine partnership, millions of Europeans are now becoming the co-producers and managers of their own health care. Given that most care, some 80 per cent, is definable as self-care, research has demonstrated that with better informed people, visits to GPs can be reduced by more than 40 per cent and hospital admissions can fall by 50 per cent.⁵⁵ Although many health professionals (concerned with issues of status and economic position) and politicians (concerned with issues of ideology and misdirected notions of 'cost containment') balk at this challenge, there is little they can do to actually stop it. At worst they can simply slow the process down.

Given the mounting pressure from ordinary people who clearly want to be able to access more consumer information, it is a shame that the DTC Directive was rejected by the European Parliament. Even though the proposal was itself far too restrictive and cautious (it only covered a limited range of treatments such as diabetes and asthma), the politicians failed to see beyond the short-term.

Nevertheless, if Europe is serious about building a dynamic, globally competitive and prosperous free market, its political leaders are going to have to recognise that open access to health information is a key, underlying ingredient. Unleashed from the shackles of corporatism and statism, health care can become one of Europe's most important growth sectors. It can not only improve people's quality of life, but it can provide valuable employment opportunities and open up new avenues of research and development.

If however, and as seems to be the case, the political class remains wedded to old and outdated notions of 'solidarity', 'market failure' and 'medical paternalism' these opportunities will fly elsewhere. If Europe's politicians fail to respect the principles of individual liberty, the benefits of a truly open and free society and basic notions of freedom of information about pharmaceutical products – Europe and its citizens will be worse off.

⁴⁸ Green, D., (1985) *Working Class Patients and the Medical Establishment*, Temple Smith, London.

⁴⁹ Ibid.

⁵⁰ Ohmae, K., *The Borderless World*, Fontana, London, 1992, pp.24-25.

⁵¹ For more on this theme and the extent to which the British government is engaging private provision across a range of services see: George Monbiot, (2001) *Captive State: The Corporate Takeover of Britain*, Pan, London.

⁵² Mohan, J., and Gorsky M., (2001) *Don't Look Back? Voluntary and Charitable Finance of Hospitals in Britain, Past and Present*.

⁵³ See: www.tradeunion-privatehealth.org.uk

⁵⁴ In addition to all of this, the rise of private health and fitness clubs and health magazines again suggests a new health consumerism.

⁵⁵ Fries, J., et al (1998) *Western Journal of Medicine* 169: 201-207. See also: Montgomery et al (1994) *The American Journal of Medicine* Vol. 97:429.

WHY THE BAN ON DIRECT TO CONSUMER ADVERTISING OF PRESCRIPTION MEDICINES SHOULD REMAIN IN FORCE

PROFESSOR ANGELA COULTER

Other contributors to this report have argued for a relaxation of the current European ban on direct to consumer advertising (DTCA) of prescription-only medications. Their case rests on three linked arguments: there is a lack of public awareness of many health problems and the potential for treating them; patients want more information about their medicines; it is paternalistic to prevent patients getting access to information that is readily available to their doctors. Let's examine each of these arguments in turn.

Promoting disease awareness?

It is indeed the case that many health problems go unrecognised in their early stages – for example diabetes, hypertension, osteoporosis, or raised cholesterol – when early diagnosis and treatment may be beneficial. In addition, people sometimes suffer health problems that they are reluctant to consult their doctors about, either because of the embarrassing nature of the condition or because they do not know that effective treatments are available: examples include incontinence and impotence. Other common problems, such as male-pattern baldness, obesity, or social anxiety may not be perceived as medical in nature, yet medications are now available which could help some sufferers. Representatives of the pharmaceutical industry have argued that they could make an important contribution to tackling this public health deficit if the current advertising restrictions were lifted to allow them to communicate directly to the public.⁵⁶

The case for increasing public awareness of methods to prevent disease progression or making it more acceptable to seek help for embarrassing problems is a strong one, but it doesn't follow that responsibility for tackling this should be delegated to commercial companies. To allow companies to

make the running in public education results in a stress on those, often minor, conditions for which there is a branded pharmaceutical product and medicalisation of normal life processes. Evidence from the United States, where this type of advertising or advertorial is sanctioned, shows that commercial interests can often lead to scare-mongering,⁵⁷ or as some critics have dubbed it 'disease-mongering'.⁵⁸ Healthy people are encouraged to think they need medical attention by the use of alarming imagery, or statistics quoted out of context, for example suggesting that minor memory lapses might be the first sign of Alzheimers disease, or citing a one in two chance of having osteoporosis leading to broken bones and dowager's hump.^{59r}

Even in countries such as Australia, where DTCA is outlawed, companies have used the media to stimulate interest in conditions for which they have a relevant product. Pharmaceutical companies, often working in alliance with doctors and patient groups, have aimed to show that ordinary processes or ailments are medical problems (e.g. baldness), that mild symptoms might be portents of serious disease (e.g. irritable bowel syndrome), that personal or social problems can be redefined as medical problems (e.g. social phobia), that risk factors can be reconceptualised as diseases (e.g. osteoporosis), and that disease prevalence is greater than it really is (e.g. erectile dysfunction).⁶⁰

There is good evidence from the USA that drug advertisements do succeed in prompting patients to initiate discussions with their doctors and that such discussions often result in prescriptions of the advertised medicines.⁶¹ⁱ This is why spending on DTCA in the USA tripled between 1996 and 2000 when it reached nearly \$2.5 billion, or 15% of the total amount spent on drug promotion.⁶² Advertising to consumers clearly succeeds in increasing sales of these medicines, but whether it leads to health benefits or harms is not known. What we do know is that it is concentrated on a few products. In 2000, just 20 prescription drugs accounted for about 60% of the total industry spending on such advertising.⁶³ These included antidepressants, antihistamines, antihyperlipidemics and anti-inflammatory agents.

The selection of treatable conditions or preparations to be the focus of DTCA does not reflect public health priorities; rather it represents companies' assessment of what they can sell by these means. Hunt has argued that five categories of products are more likely to be advertised to the public: new therapies intended to treat conditions that were formerly untreatable or only marginally treatable, such as Alzheimer's disease or migraine headaches; drugs for conditions, such as depression and hypertension, that have a history of

being underdiagnosed and undertreated, even though drug therapies were available; drugs whose lower risks or milder side effects expand the number of patients who can tolerate them; branded products that have cheaper generic or over-the-counter equivalents; and products that provide little benefit but that physicians may prescribe anyway, either out of ignorance or in order to accommodate patients.⁶⁴ While the first three of these might prove to be of public benefit, this is unlikely to be the case for the last two categories. The choice is driven by industry's need to increase demand and hence profits, not by concern for public health. As an editorial in the *BMJ* pointed out: "Do not expect to see consumers regaled with promotions about inexpensive diuretics or ? blockers, any more than about measles, mumps, and rubella vaccination or regular cervical smears."

Improving public education about disease and treatment is an appropriate public health goal, but it is not a good idea to relax the advertising restrictions to achieve this. Doing so is likely to result in a distortion of priorities to suit commercial ends and will do nothing to educate the public about the limitations of medical care.

2. Informing patients?

There is no doubt that patients want more information than they currently receive. In a recent study among representative samples of the population in eight European countries, participants expressed dissatisfaction with the amount of information they were given and indicated their desire for greater involvement in decisions about their treatment.⁶⁶ Informed patient participation in health care choices is impossible without access to accurate, comprehensive, unbiased information about the pros and cons of all available treatment options, including the option of no treatment. Just like doctors, patients need evidence-based statements of benefits and risks derived from credible sources. Information to help patients make treatment decisions must be honest and unbiased and should be explicit about uncertainties and controversies. It should present all options (including doing nothing) in a balanced way, and should be well designed, clearly structured, concise and up-to-date.⁶⁷

Inducements to patients to demand specific prescription medicines (DTCA) cannot conform to these standards. Companies whose *raison d'être* is selling products have no incentive to broadcast the existence of products produced by rival companies or to compare and contrast the benefits, risks and side-effects

of the alternatives. For most patients the starting point for their information needs is symptom control and treatment options rather than specific products. They want information about the pros and cons of alternative treatments, including detailed explanations about their condition and the likely outcomes with and without treatment. The patient who relied on drug advertisements to obtain information about which of various alternatives would best suit them would have to scan numerous individual sources and even then they would only learn about those products that the companies had chosen to advertise.

The Food and Drug Administration (FDA), which is responsible for regulating DTCA in the USA, requires that drug advertisements present a fair balance of benefit and risk information, including a brief summary of uses or indications, contraindications, warnings, adverse reactions, and overdoses. In television commercials this can be replaced by a recommendation to consult a health professional, a toll-free telephone number for further information, a reference to print information, or a web-site address. However, research evidence shows that these are not very successful at conveying information about side-effects or risks and many patients remain confused about the information presented in advertisements.⁶⁸

Pharmaceutical companies often complain that they know more about their products than anyone else yet they are uniquely subject to restrictions on imparting this information. They point to the large amount of unreliable health information now available on the internet, some of which may be more harmful than properly regulated drug advertisements. In Europe the industry has been lobbying the European Commission to allow patients to access information about their products on their websites. It is argued that this would meet patients' need for more information and would help improve compliance with medicine-taking. However, there is no evidence that the type of information that companies would provide would have any impact on compliance.⁶⁹ Advertisements tend to be superficial in their coverage of medical conditions and their treatments. They seldom educate patients about how the drug works, its relative effectiveness, alternative treatments, or behavioural changes that could augment or supplant drug therapy.⁷⁰

Advertising does not provide the type of balanced, comprehensive and comparative information that patients need to make informed treatment choices and it is not very successful at educating them about medicine-taking.

3. Countering paternalism?

The charge that it is paternalistic to prevent patients having access to information that is freely available to their doctors has some force, but this argument can't be taken too far. No one is suggesting that we shouldn't insist on a doctor's prescription before providing medications that could be harmful because it is paternalistic to do so, yet in a sense it is paternalistic. It is true that healthcare delivery is steeped in paternalism. This is a serious problem because it creates dependency and undermines people's sense of self-efficacy and ability to cope with illness or manage their own treatment.⁷¹ But advertising does not help to empower patients because it reinforces the notion that there is a pill for every ill. It is designed to create a demand for a prescription that must be written by a doctor, so it emphasises patients' dependence and undermines their ability to cope without medical intervention.

While most patients trust their doctors, this trust is not based on blind faith. Most patients want a better understanding of their illness and its treatment, but few look to pharmaceutical companies to provide this. Information produced by the commercial sector is the least trusted of any information source.⁷² People want unbiased information from independent sources that they can trust. This information should help patients understand their condition and educate them on how to prevent further illness, to care for themselves, to make informed treatment choices, and to self-manage chronic conditions. Such information can be truly empowering and there is evidence that it can have a beneficial impact on health outcomes. Promotion of information about individual products will not meet this need.

Good quality information can help to reduce the power imbalance between patients and clinicians, but health information from commercial sources is not trusted by the public and advertising prescription medicines reinforces dependence on doctors.

The way forward

What is needed is a concerted effort to make evidence-based patient information much more widely available, coupled with public education to help people critically appraise medical information. The European Commission's G10 Medicines Group has called for the establishment of a public-private partnership to develop an independent information source or gateway for patients and to ensure that the information conforms to

recognised quality standards.⁷³ There is no reason why industry could not contribute to this partnership alongside other stakeholders and indeed they should be encouraged to do so. The G10 proposal envisaged the European Commission and the European Medicines Evaluation Agency (EMA) playing a leading role, together with representatives of national governments, health insurers, health professionals and consumer groups, as well as industry.

Such an initiative could start by determining public health priorities and assembling or developing information that addresses patients' information needs in a few key areas. Demonstration projects could be established and rigorously evaluated against clear quality criteria. A great deal is already known about what patients want, but careful piloting will be required to evaluate different ways of meeting these needs. The information needs of minority groups will require special attention. In particular it will be important to examine mechanisms for disseminating information so that patients can access it at the time they need it and in a form that is comprehensible and useful to them. Information providers will need education and support to improve the quality of materials and clinicians will need training and encouragement to inform and involve patients in decisions about their care.

This is an ambitious agenda, but the rewards in terms of more informed medicine-taking and better public understanding of the benefits and limitations of medical treatments could have a profound and positive impact on public health throughout Europe.

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