



Who Wants to Know?

Direct-to-Consumer Advertising and Patient Information

CMPI

Center for Medicine
in the Public Interest

The New Vital Force in Health Care Policy

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Preface - A Modest Proposal?

Peter Pitts

In April of 2006, James Copping (Principal Administrator, European Commission Enterprise & Industry Directorate-General) had this to say about rethinking the EU Commission's position on information-to-patients:

“From the Commission's point of view, we want a system where patients can be empowered to take an equal part in health care decisions. To do that, they need more information and we all want to make high-quality information available as soon as possible. We believe that all stakeholders have a role to play to provide this information, but the tricky issue for us is to find the appropriate framework which national regulatory authorities can live with.”

And he laid out some possible ways to achieve that goal:

“The pharmaceutical industry has a lot to contribute because of their resources, skills and expertise and we have seen in the working group that the industry plays a constructive part. It's amazing to me that an industry which plays such an important part of our health care is often seen on par with the tobacco or the oil industry. It's not clear to me why this is the case, but we need to develop good working relationships between all of us. We all agree that we need good quality information, but none of us can do it alone.”

Almost two years to the day, the controversial EU-wide ban on pharmaceutical companies providing more robust and regular information to patients may soon end – although what this means, precisely, is unclear, as is what kind of information may become available.

The European commission plans to allow drug companies to give "information" about their drugs to the public on TV, the internet and in print.

The consultation document from the DG Enterprise and Industry says: "It should be possible for the pharmaceutical industry to disseminate information on prescription-only medicines through TV and radio programmes, through printed material actively distributed, through information in printed media or through audiovisual and written material provided to patients by healthcare professionals." The consultation period closed on April 7, 2008. An earlier Commission report had found unequal access to health and medicines information throughout the EU, which it said could be harmful to public health.

Leaders of the European pharmaceutical industry have once again stressed that they are not seeking, and have never sought, direct-to-consumer advertising for prescription medicines within the European Union. However, according to Arthur Higgins (President of the European Federation of Pharmaceutical Industry Associations – EFPIA -- and chief executive of Bayer HealthCare AG.), “After years of debate, we call on all European institutions to develop a patient-centered EU framework for information provision without further delay.”

EFPIA is also concerned at the EU proposals for a governance system for monitoring the information provided by the industry. The Commission suggests that the structure of enforcement could take place on three different levels – an EU advisory committee, the EU national authorities and national “co-regulatory” bodies – but EFPIA believes that this could potentially lead to a “patchwork” of very different interpretations and implementations in national laws, as it is currently the case, and thus fail to adequately address the European dimension of the current shortcomings.

Instead, the industry proposes an alternative system based on an EU-wide “health information” Code of Conduct, including effective quality assessment procedures for information, ex-post control mechanisms (with involvement of third/independent parties) and robust enforcement procedures in case of breaches including sanctions as well as fines. Such a Code could work alongside and complement the legislative change envisaged by the European Commission later this year.

But facts are stubborn things. I felt obligated to point out that DTC advertising in the United States, according to many different research studies (including some done by the U.S. Food and Drug Administration) drives patients to visit their physicians, creates an environment for more robust doctor/patient conversations, enhances compliance, destigmatizes diseases such as depression, and does NOT increase prices.

And there are also larger issue at play — that of Free Speech. Having theses conversations at a time when Europe is regularly parsing what “Free Speech” means (David Irving, Ken Livingston, etc.) makes developments in the EU even more, shall we say, stimulating.

The Danish prime minister recently said (in the wake of the cartoon scandal) that “Freedom of Speech is absolute. It is not negotiable.” That’s a good place to start when discussing ItP with the folks in Brussels.

All is not quiet on the Western Front.

Bouquets to MEP Jorgo Chatzimarkakis, one of the EU Parliament's three representatives on the HLPF, who finds the current information ban on medicines unacceptable. "I can understand a ban on advertisements but I can not agree on the ban on information, which leads us to a situation where patients are obliged to surf around the Internet to look for information on medicines. Citizens can not be deprived of information by their own governments on such crucial issues as one's health," he argues.

And brickbats to Health Action International (HAI) who claims, “there is no health information gap in Europe.” HAI disallows with a wave of their hand any useful participation by the pharmaceutical industry in providing patient information because of a “natural conflict of interest.” How very Rousseau. But concepts of natural liberty notwithstanding, HAI offers up a lot of the usual anti-industry accusations without even a scintilla of evidence.

And who does HAI consider excellent sources of patient information? IQWiG (Germany) and NICE (UK) to name two.

HAI waves the usual banners of “evidence-based medicine,” “rational use of medicine,” and the “over-medicalisation of the European population.” And they are very clearly adherents to the Precautionary Principle of “doing nothing until you know everything” (not surprising since one of their major funders is the Rockefeller Foundation).

“For each option (of type of medicine) patients should be able to clearly identify benefits (degrees of clinical effectiveness on important outcomes, convenience, etc.) and harms (potential side effects, disturbances of personal and social life, etc.). Yes – and every taxpayer should have a deep and profound understanding of the tax code. How about this: – let patients have access to information from every source and then let them speak with their physicians. That’s when good things happen.

This paper, by CMPI’s Paris-based senior fellow Jacob Arfwedson, reviews recent debates in the European Union and the United States. Hopefully, it will help policy makers to realize that information is power and that empowering consumers is a good way of improving the quality of health care.

Introduction

The transition currently taking place in the health care debate in developed countries from one-size-fits-all diagnostics and treatments to individualised care poses a major problem of efficient communication between the actors involved.

In the western Welfare States, the individual known as the patient is progressively evolving into an enlightened consumer of health services. And she is increasingly equipped with data from various sources, demands full disclosure of treatment options, performance ranking of hospitals and clinics, and generally behaves like a customer entitled to quality service and value for money, based on her own choices. This development towards patient empowerment in terms of market-based and global alternatives requires more information about available options. Hence an increased policy interest in how public and private providers of health care deliver information about their services. The issue is here to stay.

This paper will examine the status of the discussion on information to patients in the United States, New Zealand and the European Union. The overall objective is to review recent research and policy debate on direct to consumer communication (including advertising) as well as recent surveys polling patients, physicians and political decision-makers. The major argument is inspired by the Hayekian insights on market processes (information is a discovery procedure essential to competition) and by the Public Choice school (in terms of the constraints): the stakeholders involved in the quest for information all have their own interests and budgets to defend. Therefore, the outcome of the discussion should also be appreciated in terms of political influence with all the positive and negative inputs this entails. Last but perhaps most importantly, this is an issue of freedom of speech and free access to information for consumers and producers alike.

The goal is to provide a balanced account by assessing the perspective of increased access of patients to relevant information on their conditions. However, this objective will stress the fact that policy and regulations will only improve as long as the exercise of opening the market for information is allowed to take place. In other words, a rigorous analysis and serious discussion will only be useful if the information exchange does occur.

The distinction between information and promotion is prevalent in the discussion, albeit dubious when put to the test with consumers. Research shows the limit is fluid as in any issue dealing with advertising which is one particular form of information. We will sometimes use the term “consumer communication” to encompass the two. Indeed,

communication broadly speaking is often used for persuasion; this applies to our discussion as well, although it is not intended as advertising.

The study has been conducted on the assumption that the reader (like today's health consumers) is capable of absorbing and judging information critically. The contents have not been approved by any government or regulatory institution. It is the author's hope nevertheless that this absence of endorsement by elected officials or administrators will help the interested public in its belief in forming its own opinions.

We will first examine the policy debates in the EU, the USA and New Zealand to provide a backdrop to the principal arguments. Second, we will look at the nature of advertising and the profile of stakeholders. A third chapter will deal with the debate on advertising as a form of patient information. In conclusion, we will survey perspectives for consumer communications in health care, and the policy debate on patient concerns.

Who Wants to Know? Direct-to-Consumer Advertising and Patient Information

by Jacob Arfwedson

Executive summary

- The transition currently taking place in the health care debate in developed countries from one-size-fits-all diagnostics and treatments to individualised care poses a major problem of efficient communication between the actors involved.
- In the western Welfare States, the individual known as the patient is progressively evolving into an enlightened consumer of health services. And she is increasingly equipped with data from various sources, demands full disclosure of treatment options, performance ranking of hospitals and clinics, and generally behaves like a customer entitled to quality service and value for money, based on her own choices. This development towards patient empowerment in terms of market-based and global alternatives requires more information about available options. Hence an increased policy interest in how public and private providers of health care deliver information about their services. The issue is here to stay.
- Although more information about any useful product or device may be considered a boon for consumers at face value, the issue of DTCA and information to patients is criticised for several reasons. First, the physician retains an essential role as gatekeeper: there is no direct purchasing relationship between producers and consumers of prescription medicines. Second, the health care systems in advanced economies involves third-party payment: consumers have little incentive to limit their consumption of medicines since government foots the bill to a large extent. Finally, the cost of medicines is intimately linked to the regulatory system of marketing approval.
- Direct-to-consumer advertising is currently authorised only in two countries: the United States and New Zealand. Despite many political and regulatory differences, a comparison between the two countries reveals some striking similarities in patients' perceptions of DTCA.
- Patient information is a major focal point of the health care debate also in Europe. But according to the EU Directive 2001/83/EC, advertising for prescription drugs

is banned throughout the European Union. This means that health consumers depend predominantly on their doctors for relevant information concerning new therapies and products.

- The outcomes of patient surveys in Europe seem in many ways contrary to official wisdom, even in terms of those organisations claiming to represent them: patients are, more often than not, experts on their conditions and well qualified to ask the appropriate questions for more and better information and can do a great deal to look after themselves.
- Communication, marketing and advertising are information tools which are an integral part of the production process. A new product may not achieve the status of economic good without consumers being aware of its existence. In other words, a product cannot exist in the marketplace unless the producer is allowed to advertise it. In this sense, information in the form of advertising is an essential factor of production for any given good, including medicines.
- The EU legislation still leaves the general practitioner in charge of direct and product specific consumer information, whereas a free market in product advertising would simultaneously let the patient access more information on a competitive basis and give her greater clout in discussing new treatments with her doctor. However, the EU ban on advertising prescription drugs is a major obstacle to such a development.
- The current experience in developing more effective and informative advertising in the United States and New Zealand have yielded tangible benefits for patients, which would not have occurred with a ban on advertising. The reason is simply that less information and data on consumer behaviour and physicians' response to DTC advertising would then have been available. In this sense, even negative results and reactions to advertising are useful, as are critical opinions in surveys. The data thus gathered may be used to improve safety regulations, professional consumer advice and GP practices. Hence, the safety concern benefits from a wider array of information sources; restricting or banning advertising is not a solution that would increase consumer influence.
- The globalisation of markets is set to define health care in the coming decades, since consumers are becoming well aware of existing options, nationally and internationally. The consumer revolution will increasingly depend on patients voting with their feet through health tourism, than on political reform agendas which are by nature inert. This pressure will be brought to bear on existing systems through market forces, as consumers thanks to improved information progressively opt out of national services, by seeking treatments elsewhere, especially within the European Union.

I – The Policy Framework: Evaluating Experiences of Direct to Consumer Communication

This chapter will look at recent experiences in DTCA and patient information, proceeding from the most to the least tolerant regimes of this practice, i.e. the United States, New Zealand and the European Union.

It should be stressed that DTCA occurred both in the United States and in New Zealand by default: no legislative provision explicitly prohibited the use of consumer advertising. Yet, it is increasingly under fire from various interest groups.

Although more information about any useful product or device may be considered a boon for consumers at face value, the issue of DTCA and information to patients is heavily criticised for several reasons. These will be examined in greater detail in chapter 3 but will appear indirectly in the following sections. They concern the specificity of the pharmaceutical market which may be summarised in three points. First, the physician retains an essential role as gatekeeper: there is no direct purchasing relationship between producers and consumers of prescription medicines. Second, the health care systems in advanced economies involves third-party payment: consumers have little incentive to limit their consumption of medicines since government foots the bill to a large extent. Finally, the cost of medicines is intimately linked to the regulatory system of marketing approval.

The United States

The history of direct-to-consumer advertising of medicines is relatively short. The main reason is that for most of the 20th century, the products available were relatively few and not very sophisticated. The first federal legislation on prescription and over-the-counter medicines was the Pure Food and Drugs Act (Wiley Act, 1906). But it did not concern advertising as such and did not prohibit false claims about the product not appearing on the label, which led to safety concerns. The Wiley Act was replaced by the Federal Food, Drug and Cosmetic Act (FDCA) in 1938.

From 1914 to 1962, regulation of drug advertising was in the hands of the Federal Trade Commission (FTC); in 1962, the Harris-Kefauver amendments transferred this responsibility to the Food and Drug Administration (FDA); the regulation of OTC drugs promotion remained with the FTC.

Prescription drug advertising aimed primarily at physicians who detained a monopoly on choosing medicines for their patients. But as patients became more involved with their treatment, drug promotion started to include consumers. The first print advertisement appeared in 1981 by Boots for the product Rufen, followed by a Merck product, Pneumovax.¹ Rufen (arthritis pain) was advertised on television in 1983 and the first

¹ “The Development of Direct-to-Consumer Prescription Drug Advertising Regulation”, Food and Drug Law Journal, vol. 57 nr 3 (2002).

brand-name advertisements were published in consumer magazines in the late 1980s. Following the surge of advertisements, the FDA decided to impose a moratorium in September 1982 to allow time for researching the issue. The moratorium was lifted in 1985 and the FDA published its position on DTCA: advertisements must meet the same legal requirements as those targeting physicians. Ads are required to include the generic name, they must refer to facts only and not be false or misleading. In particular, ads must contain a “brief summary” of risk information (side-effects and contra-indications).² One FDA study had shown that consumers tended to absorb more information on benefits than on risks. (This claim has been the subject of numerous surveys and studies in recent years, as we shall see.)

At the time, the FDA recognised three categories of prescription drug advertisements: 1) reminder advertisements³ (which mention the brand name, but not specific information about the product or the condition the drug treats); 2) help-seeking or disease-oriented advertisements (describing symptoms and inciting patients to see their doctor, without mentioning the product name); and 3) product-claim or indication advertisements (which carry the name and indication and are subject to the brief summary and fair balance requirements).

A major change occurred in 1997 with the publication of the FDA draft guidance on direct-to-consumer advertising to facilitate broadcast ads.⁴ The brief summary requirement had shown to be impractical for television and radio, and this was replaced by “fair balance and adequate provision” of approved product labelling.⁵ This meant providing full information on side-effects and contra-indications by supplying a toll-free telephone number, a web address or reference to a complete print advertisement. This provision partly accounts for the surge in television ads which went from representing 13.5% of DTC in 1994 to 63.8% in 2000.⁶

Although DTCA still represents a small proportion of overall drug promotion⁷, the considerable growth has generated a debate which may be summarised as “an inherent conflict of interest between the legitimate business goals of manufacturers and the social medical and economic needs of providers and the public to select and use drugs in the most rational way”.⁸ Also, erroneous statistics circulate about the amount spent on promotion of pharmaceutical products relative to R&D spending⁹: for the US market

² *Idem*, p.424.

³ Reminder advertisements were voluntarily banned by PhRMA The guidelines were issued in 2005.

⁴ “The advertising of pharmaceuticals direct to consumers: a critical review of the literature and debate”, F. Auton, *International Journal of Advertising*, 23 (2004).

⁵ Full document available at : <http://www.fda.gov/cder/guidance/1804fnl.htm>

⁶ “Evaluating the Welfare Effects of Drug Advertising”, *Regulation* (Spring 2006)

⁷ 12% of total promotional spend in 2002, according to IMS, cited in Auton, p. 17.

⁸ *Clinical Pharmacological Evaluation in Drug Control*, WHO 1993 (cited in “Direct-to-Consumer Pharmaceutical Advertising”, *Archives of Internal Medicine*, 23 February 2004)

⁹ Cf. a WHO document indicating that companies spend “one third of all sales revenue on marketing their products – roughly twice what they spend on research and development”.

(<http://www.who.int/trade/glossary/story073/en/>)

(2003) this amounted to \$ 30.2 billion for research and development against \$ 25.3 billion in total promotional spending (DTC represented \$ 3.3 billion).¹⁰

US surveys on DTCA

A number of surveys have been carried out over the last decade, mainly examining the impact on patients and physicians. These provide interesting data on the demand for information and consumer attitudes; but as one article underlined, they may be criticised for failing to reply to “the fundamental question: does DTCA change actual behavior or improve health outcomes?”¹¹ It should be stressed that survey results evolve rapidly, which is another reason for pursuing the quest for better information.

Indeed, there is little research available on the health effects of DTCA; but what recent surveys tend to show is that patients increasingly consult their doctor as a result of seeing advertisements. According to a national survey of US patients, 35% of participants discussed DTCA with their physicians. Out of this proportion, 25% received a new diagnosis and 43% of these were considered high priority.¹²

The survey also examined the relative importance of information sources which prompt patients to discuss their health with a physician. 51% of patients cited friends and family, 40% broadcast media, 34% print media, 33% doctors’ pamphlets, 33% another doctor, 16% the Internet and 17% were influenced by their pharmacist.¹³

According to an FDA survey, between 3 and 5% of all doctors’ visits in the United States take place specifically because the patient saw a DTC advertisement. It is frequently mentioned that physicians feel “pressure to prescribe” a particular advertised product. But the FDA panel then discovered that what was really involved was time pressure. In other words, DTCA seems to inspire patients to ask more questions and also take time to inform themselves before seeing their physician. Overall, 40% of physicians said that DTC advertising has a very or somewhat positive effect; 32% thought that advertising has a somewhat or very negative impact. 28% said DTCA had no impact at all.¹⁴

In September 2003, the FDA convened another public meeting¹⁵ with a number of stakeholder organisations to present research on DTC advertising and to examine its effect on public health. The conclusions of the FDA surveys of patients and physicians in 2002 were that:

¹⁰ According to the Phrma website : http://www.phrma.org/key_industry_facts_about_phrma/1/ (accessed 7 July 2006).

¹¹ Regulation (Spring 2006), p. 60.

¹² “Consumers’ Reports On The Health Effects of Direct-to-Consumer Drug Advertising, J. Weissman et al, Health Affairs, February 2003.

¹³ Idem, p. 87.

¹⁴ “Consumers and Health Information: Is Knowledge Really Power?” (Amigo Society/Stockholm Network, Brussels, March 2006)

¹⁵ Full document available at : http://www.fda.gov/cder/ddmac/DTCmeeting2003_presentations.html.

A similar event was organised in 1999.

- DTC advertising increases awareness of possible treatments
- DTC advertising may convey information about benefits better than about risks
- The brief summary is not sufficiently consumer-friendly
- Doctors remain the number one source of information about drugs and treatments
- Brand-specific drug requests are frequently accommodated (a vast majority of patients asking about a brand have the condition in question)
- Physicians are evenly divided about overall impact of DTC ads on patients and practice (see above).

The results of other surveys presented at the FDA public meeting were varied, but there was some common ground on the following points:

- consumer advertising is recognised as such, i.e. a sales approach¹⁶
- about one third of consumers discuss advertised products with their doctor (this has remained unchanged since 1997)¹⁷
- advertising promotes patient involvement and shared decision-making¹⁸

But there were also more critical contributions, mainly on the need to strengthen information about risks involved:

- better comprehension of information on side-effects/inappropriate prescribing¹⁹
- difficulty in understanding drug information²⁰
- comprehension of benefits²¹

The meeting concluded that, while there are risks for inappropriate prescription behaviour based on patient demand, there is potential for raising awareness of yet undiagnosed conditions and a need for further research on the impact of advertising concerning compliance. The fact that survey results evolve rapidly – most notably, the confidence in the FDA’s effectiveness has fluctuated widely recently – is a further argument for regular and comprehensive research.

DTCA and health care costs

A frequently invoked argument against increased use of consumer advertising concerns the costs: this includes both the costs of advertising as such (estimated at \$ 4.65 billion for the US market in 2005)²² and the higher costs associated with increased prescribing. More importantly, critics argue that the cost of DTCA will be recouped by manufacturers

¹⁶ <http://www.fda.gov/cder/ddmac/P1golodner/index.htm>

¹⁷ <http://www.fda.gov/cder/ddmac/P1Slaughter/index.htm>

¹⁸ <http://www.fda.gov/cder/ddmac/p3young/index.htm>

¹⁹ <http://www.fda.gov/cder/ddmac/ATT424066/index.htm>

²⁰ <http://www.fda.gov/cder/ddmac/P5Roberts/index.htm>

²¹ <http://www.fda.gov/cder/ddmac/P5Woloshin/index.htm>

²² TNS Media Intelligence, cited in “The Science of DTC”, MM&M April 2006, p. 39.

through higher prices. Even if this were correct, the problem has less to do with advertising as such than with the larger issue of government health care provision.

Socialised health care, through near-universal insurance plans (through the employer in the US) and mandatory coverage through the state in New Zealand and Europe is by nature skewed towards over-consumption of services, including medicines. As noted by two American analysts, US patients suffer from an over-reliance on health care coverage:

“Rather than have consumers evaluate the costs and benefits of different types of coverage, government actively hides the full cost of coverage from consumers. As a result, consumers demand more generous coverage. (...) First, the federal and state governments grant special tax treatment to employer-provided health insurance. As a result, most Americans obtain health coverage through an employer. (...) Second, government provides health coverage to tens of millions of Americans through government programs. These programs hide the cost of coverage from the beneficiaries by passing the cost on to taxpayers. The cumulative result is that roughly 86 cents of every dollar spent on medical care in the United States today is financed through a third party. Government itself finances nearly half of all medical expenditures. (...) By this admittedly crude measure, America’s health care system is more socialized than many others.”²³

Worse, the overuse of health care due to third party payment does not necessarily translate into improvements. The RAND Health Insurance Experiment compared utilisation between two groups of patients, where the first was offered “free” health care, and the other had to make choices between health care and other uses until a certain limit in out-of-pocket expenses. As a result, the latter reduced its expenditure by 25-30% compared to the group which enjoyed full coverage. Conversely, the group with comprehensive coverage consumed 43% more medical care, although this provided no measurable additional value.²⁴

In 1965, US patients paid 93% of the cost of prescription drugs themselves; by 1990, this figure had fallen to 63% and in 2002 to less than 25%.²⁵ As remarked by one specialist, “the dominant role of third-party payments creates moral hazard on the part of insured patients and their physicians, neither of whom have an incentive to balance benefits against the full costs of drug therapy”.²⁶

Hence, over-consumption is to a large extent due to a fundamental lack of information to patients, but also to doctors. Patients have little incentive to shop around, since they are neither able to find price information, nor required to pay the full cost if they did. On the other side, physicians and providers generally cannot accurately assess demand, since their payment depends not on the quality of their services, nor the readiness to pay; but on objectives set by insurers, employers and government. As the Federal Trade

²³ *Healthy Competition : What’s Holding Back Health Care and How to Free It*, M. Cannon, M. Tanner, Cato Institute, 2005, p. 46.

²⁴ *Idem*, p. 52.

²⁵ *Idem*, p.52 and Calfee (2002) p. 78.

²⁶ “The Role of Marketing in Pharmaceutical Research and Development”, *Pharmacoeconomics* 2002:20.

Commission and the Department of Justice remark, “The public has access to better information about the price and quality of automobiles than it does about most health care services.”²⁷

Against this background, critics are partly right when pointing out that pharmaceutical marketing is “different”. But this has less to do with the specificity of medicines as a product than with the regulatory framework and the various gatekeepers which drive a wedge between the consumer and the market. As one author observes, pharmaceutical marketing is “unusually difficult and expensive. These impediments arise mainly from regulation and the dominant role of third-party payments for health care, together with great uncertainty about potential demand and the long time lag between demand assessment and the introduction of new products”.²⁸

The pharmaceutical industry has had to face severe criticism in recent years on DTCA practices, in particular on the need for more accurate risk/benefit information in advertisements. This seems to have produced some positive feedback, as the FDA has recently been submerged by demands for approval of new advertising which aims to include and take into account past experience. The trial-and-error exercise involved includes more “data-driven” promotional campaigns which supposedly give greater weight to consumer perception and understanding of essential product information. As one industry representative put it: “We know that people use four or five different information sources before raising something with a doctor.”²⁹

A renewed advertising drive which includes and further improves content in consumer communications will hopefully take into account the immense growth of information sources, and the increasing literacy and expertise of patients for very specific needs. These developments will constantly push producers to improve clarity and risk/benefit accounts in advertising, especially in terms of chasing bad information off the Internet.

New Zealand

New Zealand is the only other nation worldwide to authorise DTC advertising, and its experience provides valuable insights into marketing and information of pharmaceutical products on several scores. This exercise may come to a halt eventually, as an agreement between the NZ government and Australia foresees a ban on consumer advertising. Meanwhile, the past decade has provided a host of data especially in terms of consumer surveys.

The New Zealand experience in DTCA began in the early 1990s, but differs from the US model as it is based on a regime of self-regulation of advertisers. The contents of promotional material is regulated by two statutes: the Medicines Act (1981) and the Medicines Regulations (1984). The former details the compulsory items in any

²⁷ Cannon and Tanner, p. 54

²⁸ Calfee 2002, p. 84.

²⁹ “The Science of DTC”, MM&M April 2006, pp. 41-42.

advertisement, such as details on the active ingredients, authorised use, appropriate precautions as well as known contra-indications, poisonous effects or adverse reactions. The latter defines “therapeutic purpose” and what may not be communicated in advertisements (these must not claim that the product is infallible and may not include testimonials).³⁰

Another important factor for our discussion is the introduction of the New Zealand Bill of Rights Act, providing explicit protection of freedom of speech (this includes so-called commercial free speech, i.e. advertising). This provision may be compared to the First Amendment in the United States’ Constitution and thus a major safeguard for DTC practices.

As DTCA emerged in the early 1990s, the pharmaceutical industry was criticized for seeking to boost demand of so-called lifestyle drugs. The advertising industry responded by formulating a code for therapeutic advertising which covers prescription medicines but also every product with therapeutic claims. This code is managed by the Advertising Standards Authority (ASA) which includes the Advertising Standards Complaints Board (ASCB). Any advertisement violating the codes is removed until compliance is met. The media are represented on the Board and refuse to publish any advertisements which have been found in violation of the rules; this ensures total compliance.

In addition, the Association for New Zealand Advertisers launched the Therapeutic Advertising Advisory Service (TAAS) in 1998 to further improve compliance. In 2000, this was transformed into the mandatory Therapeutic Advertising Pre-vetting Service (TAPS) which provides preview and approval of advertisements. Any ad lacking a TAPS number will not be publicized.³¹ Investigations must be triggered by a formal written complaint. All broadcast advertisements have to be approved by TAPS since November 2000.³²

The two countries also have very different health care systems: New Zealanders benefit from government subsidies for both acute care and doctors’ visits and prescriptions. US patients under the age of 65 mostly finance their health care out of pocket or through the employer health insurance; the brunt of medical bills are paid by employers or insurers.³³

Despite these differences, a comparison between the two countries reveals some striking similarities in patients’ perceptions of DTCA.

³⁰ “DTC advertising of prescription medicines in the United States and New Zealand : an analysis of regulatory approaches and consumer responses”, Hoek, Gendall and Calfee, *International Journal of Advertising* 2004, p. 199.

³¹ *Idem*, pp. 204-205.

³² “Direct to Consumer Advertising of Prescription Drugs in New Zealand: For Health or For Profit?” Report to the Minister of Health supporting the case for a ban on DTCA, Prof. Les Toop et al. (Christchurch, Dunedin, Wellington and Auckland Schools of Medicine, February 2003)

³³ The proportion of Americans insured through an employer was 60.4% in 2003. *Healthy Competition*, M. Cannon and M. Tanner, Cato Institute, 2005 (p. 61)

Consumer and Physician Surveys

As in the United States, surveys have been undertaken to poll patients and healthcare professionals alike on their views on DTCA. As pointed out by the authors of one major survey, the impact of DTCA “should be viewed in the context of wider societal changes such as aging populations and the advocacy of more aggressive treatments for some medical conditions such as cholesterol”.³⁴ Also, the New Zealand data is “particularly relevant for countries with universal (government funded) health systems” and will therefore be of help in the section dealing with the European discussion.

The empirical results³⁵ concerning the impact of DTCA on adult perception of advertised medicine and the relationship with health professionals may be summarised as follows.

- A large proportion of consumers take both prescription medicines and alternative or complementary medications at the same time, but do not inform their physicians
- Consumers are aware of but don't read the small print in advertisements (except people with chronic conditions)
- Consumers are likely to seek more information on diagnosed conditions and treatment options from various sources after rather than before a diagnosis has been made and treatment begun, rather than reacting exclusively to an advertisement.
- Advertising is a minor incentive to discuss existing or new conditions; the discussion takes place at a regular appointment in a very large majority of cases.
- 59% of respondents received a prescription after discussions which had been spurred by an advertisement. The prescription often was not the product advertised.
- Patients expect to receive a full explanation of any treatment and to participate in the decision-making.
- Patients think that DTC advertising makes them feel more comfortable with their medication and its safety/benefits, more likely to comply with prescriptions and getting these refilled (although the proportion is lower than in equivalent US studies).

³⁴ “Consumer Perspectives on Medications, Medical Professionals and the Impact of the Promotion of Medications Direct to Consumers”, Dr. Lynne Eagle, Assoc. Professor Kerry Chamberlain, Massey University (Auckland, NZ) 2003.

³⁵ *Idem*, p. 7.

- Attitudes towards DTCA are mixed: the information potential is recognised, but also the need for more balanced information. Advertising is not considered as a burden on the patient/doctor relationship as consumers are attached to the physician's pre-eminence in providing information on treatment options.

A concurrent study by the same authors³⁶ examines the attitudes of the medical professions (general practitioners, pharmacists and practice nurses) towards DTC advertising, largely reflecting the results from the consumer survey. It seems that few doctors' visits are the result of DTC marketing, and even fewer are triggered by information found on the Internet. The health professionals cite only limited pressure from patients to supply specific products: the latter are as likely "to receive an alternative brand or a suggestion to seek medical consultation as to receive the requested medication".³⁷ All three categories were positive to requests for advertised products, but concerned with the insufficient information on risks and side-effects, as well as the underlying profit motive.

Towards a Ban on DTCA?

Despite numerous surveys indicating rather positive attitudes to DTC advertising, there are also important constituencies criticizing the experience, including a movement calling for a complete ban. This debate reached an apex in 2003, when a group of academics published a report to the Minister of Health advocating that DTCA be prohibited. This followed a survey which had been sent to general practitioners and to consumers. The group also enlisted support from several NZ professional and consumer organisations. In conclusion, the authors stated that:

- There is evidence of harmful effects, but none on the benefits of DTCA on health.
- DTCA cannot provide objective information on risks and benefits; it overstates efficacy and minimises side-effects and safety issues.
- DTCA is very effective at selling medicines.
- DTCA has a negative effect on the patient/doctor relationship and promotes medicalisation of normal health and ageing.

However, the expected impact of the report at the lobbying level was skewed by a serious methodological flaw. The survey was sent out with a covering letter which explicitly announced that the objective was the elimination of DTCA. As noted by Hoek et al, "predictably, the results of this census supported a ban on DTCA, although these results

³⁶ "DTC: Dogma, Doubts, Diversity and Divergence: Perspectives from the Medical Professions Regarding the Impact of the Promotion of Medications Direct to Consumers", Dr. Lynne Eagle, Assoc. Prof. Kerry Chamberlain, Massey University (Auckland, NZ) 2003

³⁷ *Idem*, p. 2.

must be interpreted with considerable caution given the extraordinary bias in the covering letter”.³⁸

The Advertising Standards Authority (ASA) also commissioned an independent report³⁹ to review the report by Toop et al which provides a point-by-point rebuttal, including responses from the pharmaceutical companies targeted.

The argumentary will be examined more extensively in chapter 3, but some elements are particularly relevant for the New Zealand context.

First, as noted by the ASA report, the Toop document (despite the credentials of the authors) is not an academic document but a partisan approach aimed at gathering support for a ban on DTC advertising. Second, the case for a ban (based on the Toop report conclusions) is largely unfounded, be it in terms of cost arguments, patient or physician responses. Third, the current system of self-regulation by advertisers is subject to precise rules and no objective evidence in the report supports a ban on these grounds.

Former Minister of Health Annette King wanted a ban to take effect at the same time as the Trans-Tasman medical safety agency was established jointly with Australia in 2007. At the time of writing, the NZ government reportedly lacks sufficient support for this to happen. Because Australia has a Disease State Advertising regime, DTCA may be restricted to this type of communication.⁴⁰

The conclusions of Hoek et al deserve a mention: DTCA is effective from a consumer perspective and seems helpful for discussions with physicians. Whereas there is a good deal of scepticism towards DTCA claims, large majorities (both in the United States and New Zealand) think that advertising provides information about the benefits of medicines. Surveys in both countries suggest that overall, consumers have no significant problems with DTC advertising. As stated by the authors: “(...) consumers themselves do not share many of the concerns raised on their behalf”.⁴¹

However, this controversy provides a host of interesting arguments which are vital for the European debate, and empirical evidence which unfortunately are lacking in the EU context.

³⁸ Hoek, Gendall and Calfee, p. 209.

³⁹ “DTC Advertising of Prescription Drugs in New Zealand: Professors’ ‘Protest to Government’ Placed under the Microscope, Advertising Standards Authority/Saunders Unsworth Limited, April 2003

⁴⁰ Communication with Jeremy Irwin, Executive Director, Association of New Zealand Advertisers (10 July 2006).

⁴¹ Hoek, Gendall and Calfee, p. 222.

The European Union

Unlike the United States and New Zealand, the European Union prohibits DTCA. Therefore, the previous chapter is particularly relevant for reviewing the debate on consumer advertising in the 25 member countries of the EU; and there is some evidence that the policy environment is changing towards a greater understanding, if not for DTCA, then at least for some leeway in terms of manufacturer contributions to the discussion.

Patient information is a major focal point of the health care debate also in Europe. But according to the EU Directive 92/28, advertising for prescription drugs is banned throughout the European Union. Advertising is defined as “any form of (...) information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products”.⁴² Which means that health consumers depend predominantly on their doctors for relevant information concerning new therapies and products.⁴³

In July 2001, the European Commission proposed a change to the directive, making more non-promotional information available within a 5-year pilot programme for three long term chronic diseases: HIV/AIDS, diabetes and asthma. The proposal was rejected by the European Parliament on 23 October 2002 by 494 votes to 42. The EU Ministers of Health followed suit in June 2003, voting by 33 votes to 18 in favour of an unchanged Directive. This underlines once again the resistance to more open and consumer-driven communications on health which are not approved beforehand by legal and administrative bodies.

The DG Directorate for General Health and Consumer Protection (SANCO) established the EU Health Policy Forum (EHPF) in November 2001. The Forum set up a working group on health information in late 2003 which published its recommendations in May 2005.⁴⁴ While recognising the vital nature of health information, the document restated and confirmed current policies: “In extending its comments to include commercial advertising the Forum is seeking to underline the role advertising can play in influencing health related choices. **Recognising the impact of such advertising the Forum argues that no relaxation of current EU legislation which prohibits the advertising of prescription only medicines should be envisaged.**”⁴⁵

⁴² European Directive 92/28/EEC, henceforth 2001/83/EC, art. 88 (http://europa.eu.int/eur-lex/en/consleg/pdf/2001/en_2001L0083_do_001.pdf):

“1. Member States shall prohibit the advertising to the general public of medicinal products which:

(a) are available on medical prescription only, in accordance with Title VI; (...)

3. Member States shall be entitled to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.”

⁴³ Total European non-branding DTC advertising (2004) was estimated at \$ 85 million (or €69.2 million) according to Pharmaceutical Executive Europe (1 May 2006).

⁴⁴ “Recommendations on health information”, EU Health Policy Forum, May 2005.

⁴⁵ *Idem*, p. 2 (bold in original).

Nevertheless, patients as consumers are getting impatient to access better information on treatments and will not take no for an answer, regardless of safety issues or budget constraints. Indeed, the right to information is clearly inscribed in the European Charter of Patients' Rights: "Every individual has the right to access all kind of information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available."⁴⁶

This should, in theory, give patients unlimited access to health information, regardless of provider. And it does; with one important exception: manufacturers of medicines (pharmaceutical companies) are excluded from this process.

The reasons for this will be reviewed in the next chapters, after having examined the nature of advertising and its role. First, we will review some of the prevalent arguments in the European debate on DTC advertising.

Who should know? Who should inform?

Following the EU policy decisions in 2001, the Amsterdam-based organisation Health Action International organised a seminar on the issue which offers an interesting cross-section of the discussion which is still demonstrative of European attitudes, at least in terms of organisations which purport to voice the opinion of major constituencies. It should be noted however that only one patient group and one consumer organisation were included.⁴⁷ Another event on patient reporting on adverse reactions to medicines was held in 2005.⁴⁸

Generally, increased information to patients is considered a benefit, with a definitive proviso: this must come from an objective source. On various grounds, the overwhelming majority of participants reject the US experience of DTCA, but with different caveats. The stress is on the need for non-commercial information, including the clear message from the European industry representative indicating that DTCA is not on the agenda.⁴⁹

The core issue is that patients indeed require more information about their conditions and available treatments. However, the line between advertising and other information remains undefined: according to one author "Information that is used as a sales tool is advertising." But he goes on to say that "direct to consumer information is vital for patients and good health care".⁵⁰

⁴⁶ Cf. <http://home.online.no/~wkeim/patients.htm>.

⁴⁷ "Providing prescription medicine information to consumers : is there a role for direct-to-consumer promotion ?", Health Action International symposium, Brussels, January 2002.

⁴⁸ "Patients' reporting of adverse reactions", Health Action International, May 2005.

⁴⁹ HAI 2002, pp. 30-32.

⁵⁰ *Idem*, p. 26 (Mr. Leon Wever, Dutch Ministry of Health).

One dissenting voice remarked: “One has to ask why efforts at providing information haven’t worked very well. And if in fact patient information is available, then it can offset any promotion given by the industry. It seems to me that people are afraid to allow direct-to-consumer advertising in Europe because there is nothing to oppose it.”⁵¹ The industry representative stressed his opposition to advertising, while insisting that “pharmaceutical manufacturers should be able to inform patients adequately about the benefits and risks of their products”.⁵² However, this supposes an amendment to the EU Directive, as almost any communication by industry directly to consumers may be considered advertising.⁵³

A second event was organised in May 2005 to discuss patients’ reporting of adverse reactions. The report provides useful data on reporting systems in EU countries (UK, Denmark, Sweden and the Netherlands). It is worth noting that the commentary following the survey results stress the use of “commercials” in highlighting the information provided. In the Netherlands, the system run by the consumer group DGV is promoted by “posters and cards in pharmacies and libraries, through commercials on local and regional radio stations and advertisements in local newspapers and the trade press for physicians and pharmacists”. Further, the report points out that “media coverage also shows that a little bit of publicity can go a long way to raising awareness of the possibility for patients to report”.⁵⁴ Indeed; this insight applies to DTCA as well.

The EU Interest for DTCA is Growing

This is useful data and seems to reinforce the conviction that more efficient information systems can genuinely improve things for patients. As we have seen, a major obstacle in Europe to gathering data on consumer attitudes to advertising on prescription medicines is the EU Directive which bans it. However, we will briefly mention two exceptions to the rule.

One is provided by an article published in 2008 comparing the New Zealand DTCA experience with that of Belgium.⁵⁵ Questionnaires were sent to general practitioners, pharmacists and patients; but because of the EU prescription drug advertising ban (which includes Belgium) questions concerned only OTC products, with a number of hypothetical questions concerning prescription medicines added. The results show that there are several similarities in the perception of DTCA: it does not seem to affect the refilling of prescriptions; physicians do not report additional pressure in prescribing or selling; both patients and medical professionals think the quality and reliability of DTCA

⁵¹ *Idem*, p. 29 (Dr. Philip Brown, SCRIP, United Kingdom).

⁵² *Idem*, p. 31.

⁵³ According to a decision by the Conseil d’Etat (France) in March 1979, even news articles may be considered advertising.

⁵⁴ “Patients’ reporting of adverse reactions”, Health Action International, May 2005, pp. 4 and 7.

⁵⁵ “Attitudes and Self-Reported Behaviour of Patients, Doctors and Pharmacists in New Zealand and Belgium Toward Direct-To-Consumer Advertising of Medication”, Dens N., Eagle L.C., de Pelsmacker P. (University of Antwerp, Middlesex University 2006; published in *Health Communication*, vol. 23, issue 1, January 2008).

is low. The authors nevertheless conclude that overall, “DTCA does not harm the self-reported relationship between doctors, pharmacists and patients”.

Second, the extensive research project “The Informed Patient” has been conducted since 2002 at Cambridge University.⁵⁶ It shows that well-informed patients are less anxious, start their treatments earlier and follow their doctors’ advice more closely. The second report, published in 2004, presents an elaborate and detailed strategy for EU policy makers and member countries, “to more fully involve patients in their health, decision-making about treatment and in the management of their care”.⁵⁷

Notwithstanding the host of consumer and patient organisations with political presence and clout in Brussels, we may detect a new type of lobbying in the shape of better surveys devised to disseminate more widely accurate information on health consumer demand and ranking of national health care systems.

On the forefront is *Health Consumer Powerhouse*, established in 2004.⁵⁸ Its major innovative contribution to a Europe-wide benchmarking of health consumer information is the Euro Health Consumer Index, first published in 2005 (based on the experience of several national surveys in Sweden). The 2005 index presented results from 12 EU member countries, expanded to all members in 2006.

	Belgium	Estonia	France	Germany	Hungary	Italy	NL	Poland	Spain	Sweden	Switzerland	UK
Patients’ rights law	+	+	-	-	+	-	+	-	-	-	+	=
Provider catalogue with quality ranking	-	-	-	-	-	-	=	-	-	-	-	+
Web or 24/7 telephone healthcare info	-	=	=	=	=	-	=	-	-	=	=	+
Direct access to specialist care	+	=	+	+	-	-	-	-	-	-	+	-
Right to second opinion	+	=	+	+	=	=	=	-	=	=	+	-

Source: Health Consumer Powerhouse 2005 (reproduced by kind permission).

The 2005 survey examines in more detail patient access to information, detailing results from 12 countries which clearly show that patient rights have yet to be implemented in most EU member countries.

⁵⁶ Main page at: <http://www.jbs.cam.ac.uk/research/health/tip/index.html>

⁵⁷ “TIP-2: The Informed Patient – An EU Framework for Action”, p. 2.

⁵⁸ Health Consumer Powerhouse, www.healthpowerhouse.com.

The outcomes of patient surveys in Europe seem in many ways contrary to official wisdom, even in terms of those organisations claiming to represent them: patients are, more often than not, experts on their conditions and well qualified to ask the appropriate questions for more and better information “and can do a great deal to look after themselves”.⁵⁹

A similar survey by a US foundation points out that the fear that consumers are ill-prepared for greater choice is not founded, as it ignores the power of market dynamics. Consumers already possess efficient tools for surveying available options, notably through consumer magazines and web resources. As a market for health choice emerges, there will be a growing demand and supply of information tools. According to a 2006 survey by the California-based Health Care Foundation, the need for unbiased information on health has already spawned instruments of this kind. In a 2004 poll, 80% of US Internet users said they have looked for information on 16 health care topics “with increased interest since 2002 in diet, fitness, drugs, health insurance, experimental treatments and particular doctors and hospitals”.⁶⁰

1) The Commission Report on Current Practice⁶¹

The Commission Draft report results from an amendment to the Directive 2001/83/EC, adding article 88a which 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.”

Based on this, the report was supposed to examine the existing information mechanisms on EU and member states level; the needs of patients, and the role of different stakeholders. All this bearing in mind that consumers, far from being couch potatoes, are actively seeking information about their treatment options.

In the past 5 years, we have seen the following initiatives at the EU level:

⁵⁹ Health Consumer Powerhouse/PatientView 2006 survey (unpublished), p. 6.

⁶⁰ “Consumers in Health Care : Creating Decision-Support Tools That Work”, California Health Care Foundation, June 2006, pp. 12-13.

⁶¹ Available at:

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_04/draft_infopatie nts2007_04.pdf

July 2001: the European Parliament rejects proposal of more non-promotional information for HIV/AIDS, diabetes and asthma

November 2001: DG SANCO establishes the Health Policy Forum

May 2002: the G 10 Medicines group presents its recommendations

May 2005: The Health Policy Forum confirms the advertising ban and the need for more information

June 2005: Commission establishes the Pharmaceutical Forum (three working groups : information to patients, relative effectiveness, pricing/reimbursement).

As stated in the report, despite all these efforts there is still no Community legal framework for information to patients.

To simplify, there are two fundamental visions of European policy and practice: one is integration by top-down standardisation and homogenisation, i.e. one size fits all. This is largely implemented by EU directives and regulations (although health care obviously remains a national concern so far).⁶²

The other vision is that of subsidiarity, the “Cassis de Dijon” approach, where some leeway may be found for more flexible arrangements by letting practices which are approved in member countries define a competitive framework for the benefit of health care consumers. We should note that what is known as health tourism falls within this remit as well, and poses other problems in terms of cross-border regulation of care providers, insurers, etc.

Public consultation responses

The conclusions of the public consultation were published in October 2007.⁶³ It seems clear that the 73 responding stakeholders basically agree that:

- information provisions to patients should be improved, but that DTC is not on the agenda. This includes all pharmaceutical companies. One patient organisation supported DTC

⁶² Although we should note that Commissioner Kyprianou on 23 October 2007, when presenting the Commission’s Health Strategy, said that the EU should play a greater role in health care, notably in centralising facts on health and illnesses (http://ec.europa.eu/health/ph_overview/strategy/health_strategy_en.htm).

⁶³ Available at:

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_10/d-34327-summary-of-consultation-responses.pdf

But, there was considerable disagreement in the following areas:

- the distinction between information and advertising: health care professionals and pharmaceutical companies typically consider that this distinction is not clear and that clarification is needed (This seems to indicate that we need more information on advertising!)
- the role for the industry in providing information: two consumer organisations were opposed to this, as were several health professional organisations, whereas patient organisations mostly supported a greater role for industry

Perhaps more noteworthy is the reaction from the (only two) social insurance organisations providing a response:

- one criticises the draft report for overemphasis on the benefits of information and maintains the support for a DTC ban
- the second argues that information from industry is by definition promotional

This is perhaps not so surprising, considering that insurance organisations have a direct interest in keeping information away from people, lest they become aware of alternative solutions.

Concerning existing information sources, only Sweden, Denmark and the Netherlands offer a layman adapted pharmacopeia, i.e. a patient-friendly guide to existing products. Similarly, in Denmark, Finland, Norway and Sweden the national competent authorities provide information on medicines on their websites.⁶⁴

This is encouraging, but insufficient: in terms of health care information by telephone or on the Internet, this may be found on a comprehensive basis only in Belgium, Malta, the UK and Portugal.⁶⁵

As the report concludes, “a profound assessment on the perception of the different practices in Member States is not available”.⁶⁶

Online Access to Information

Out of the 23 countries responding to the survey,⁶⁷ 73 per cent provide internet access to all or some of the package leaflet and the summary of product characteristics (SPC)

⁶⁴ Draft report, p. 9.

⁶⁵ Health Consumer Powerhouse, 4 May 2007.

⁶⁶ Draft report, p. 9.

⁶⁷ 23 EU member states plus Iceland, Liechtenstein and Norway. Annex III to Commission draft report

according to the Competent Authorities. 19 member states publish the SPC online and 15 countries publish both the SPC and the package leaflet. (As we have seen, in Sweden the new package leaflet is immediately available online.)

As regards the quality of information, public-private partnerships could certainly be useful. What patients really need is the equivalent of the Michelin guide, for products and treatments. The private sector is far superior at developing quality labels, and industry organisations could certainly help in establishing a Europe-wide system, or at least standards of labelling which could be compatible within the EU.

But such a system (or systems) should not be construed as an opportunity for the EU institutions to impose certain standards or compulsory information. Only the market can provide timely information of high quality; governments are generally very bad at this.

2) High-Level Pharmaceutical Forum⁶⁸

Although the Commission report supposedly takes it into account, it is worthwhile looking at the High-Level Pharmaceutical Forum's conclusions in more detail.

The HLPF second report was published in June 2007: it reviews the progress made by the three working groups (information to patients, relative effectiveness of medicines and pricing & reimbursement policies).

In the context of socialised health care (which defines the political context of our remit in the European Union), these three strands of policy are intimately linked. I will not get into the details here, but these are three policy pillars which are brought to bear on our topic.

As a contrast to the Swedish experience, consider France which has among the strictest regulations in Europe concerning information. (Perhaps the most radical example of this was when the Conseil d'Etat banned a newspaper article on the grounds that this represented pharmaceutical advertising.)⁶⁹ Further, a common argument is that if information to the public on medicines were to increase, this would drive up costs and increase the amount spent on new medicines. And within the context of a health care system based on third-party payment, this is of course a political issue.

But we may ask if this correlation really holds: Sweden, with a more relaxed attitude to information and advertising, spends \$ 340 per capita (or 12.6 per cent) on pharmaceuticals; France spends \$ 606 per capita (or 20.9 per cent) of total health care costs.

(http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_04/draft_infopatie nts2007_04.pdf)

⁶⁸ Available at: http://ec.europa.eu/enterprise/phabiocom/comp_pf_mtng_20070626.htm

⁶⁹ Conseil d'Etat, March 1979.

Likewise, Italy has extended the advertising ban to cover also products which are reimbursed; yet in Italy pharmaceuticals represent 20.1 per cent of its health expenditure. Moreover, Italy provides no information in the survey as to why ... there is no information to patients, even at an official level!

Whom do you trust? The Health Consumer Powerhouse in Brussels conducted a survey among some 120 patient organisations in 2006. One significant question dealt with the credibility rating of various sources of information on treatment options by 2020. These are the results:⁷⁰

Sources	Number (multiple choice possible)
A) Official websites and/or telephone hotlines run by national and/or local government	88
B) Official websites and/or telephone hotlines run by EU bodies	39
C) Other non-official websites	57
D) Trained health care professionals (pharmacists, doctors, nurses, etc)	89
E) Health care providers (including hospitals)	69
F) Patient organisations	76
G) Pharmaceutical companies	27
H) Private health insurance companies	24
I) The media	43
J) Friends and family	36

The results range from the least popular (private insurance and pharma companies) to the preferred (official websites and health care professionals).

The opponents of industry as information provider are jumping with joy when they see this: pharmaceutical companies clearly have little credibility in this. But let us take the opposite stance: if industry has no say, like today in Europe, how could it possibly build credibility? How do you build trust without dialogue?

The one exception to this rule is Finland, where web-based information provided by pharmaceutical companies was let free for a year as a test, which was appreciated by patients.

As has been shown by the research project “The Informed Patient” which started in 2002 at Cambridge University, **better information means increased compliance**. Well-

⁷⁰ Health Consumer Powerhouse, Response to the High-Level Pharmaceutical Forum, 5 May 2007.

informed patients are less anxious, start their treatments earlier and follow their doctors' advice more closely.⁷¹

A corollary to the above is: what is the appropriate level for issuing rules or guidelines? In other words, where is the most effective “compliance level” for politics? To quote one of the open answers to the survey:

“All governments need to change their attitude to legislation. At the moment, there is so much legislation that the consumers don't know WHAT their rights are. Brussels is too far away; each country needs to have legislation from Brussels on how to win the trust back from their voters. One of the most frustrating problems with legislation is that if a country doesn't adhere to the rules, there is no follow-up – and this includes not only the governments themselves, but also Brussels.”

This is an admirably concise summary of the EU legislative quandary in general. Taking into account the profusion of databases across the Union, both public and private, it is difficult to see the need for an EU-directed initiative in this area. More importantly, since all markets are geared to serve national, regional and local communities, whose needs are largely determined by public policies, it would be impossible to conceive a Brussels-based database to cover the needs of 27 countries. As we have seen, patients put their trust in a wide variety of producers of information, and these will of course vary with and within the national context.

As pointed out by Health Consumer Powerhouse, “the regulator should never be at the same time the producer” of information. However, the EU does have a prominent role to play in providing guidelines and minimum standards – but not in providing the information as such.

The Pharmaceutical Forum defines the core quality principles for patient information in its June 2007 report:⁷²

- Objective and unbiased
- Patient oriented
- Evidence-based
- Up-to-date
- Reliable
- Understandable
- Accessible
- Transparent
- Relevant
- Consistent with Statutory Information

⁷¹ The Informed Patient: <http://www.jbs.cam.azc.uk/research/health/tip/index.html>

⁷² Pharmaceutical Forum, Second progress report, June 2007 (pp. 16-17.)

Please consider this list of good intentions. Then ask yourself, as a patient (or parent or relative of somebody ill) is this useful for you, and at what level? Would you check this list before rushing to the emergency room, or would you attempt to find the relevant information from your family doctor, your local hospital or clinic, websites or medical journals? It is certainly reassuring to learn that patient information should be “patient oriented” and that it should be “understandable”. In the same vein, it has been decided that a European Public Assessment Report should have a summary “written in a manner that is understandable to the public!”⁷³ Naturally, this will take some getting used to for people in Brussels.

A free and open market in information is the most effective way of achieving good results in this area. If government can help, that’s fine but certainly not a panacea, nor will it offer a comprehensive solution as effective information must always be local, decentralised and, ultimately, individual.

It is customary, in any European discussion of health care policy, to conclude that whatever we want – and this is not always clear – “we don’t want the US system”. What this is, is not very often defined, but if Europeans all agree, it is maybe not necessary. It will be more difficult to create a vision of what we do want – and perhaps especially to define who “we” are: governments, the EU, health consumers?

In terms of *policy discourse*, clearly there is no reason to expect any form of DTC to materialise in Europe in the short to medium term. At the *lobbying level*, in Brussels or in member countries, there is apparently a consensual block in favour of better information, including by industry, in some shape or form to be defined. Likewise, DTC is rejected by all relevant stakeholders.

This is what you see. What you don’t see is that *DTC is already happening*, for instance in Sweden as mentioned. Indeed, we may agree that the US model of DTC (insofar as a “model” can actually be designed for something as fast-moving and fluid as information) is not for Europe. But to the extent that DTC is today’s reality and tomorrow’s regulatory headache, the New Zealand experience is worth bearing in mind, because of its self-regulatory aspects. And finally, a greater tolerance through improved competition between a large variety of information sources would be beneficial for all.

II – The Nature of Advertising and its Stakeholders

Perhaps the most common argument against DTCA is that it is just that: advertising. This is often construed in a fictitious but powerful opposition where advertising is distinguished, or indeed opposed to, information. Therefore, we are facing a situation where the European debate vigorously defends freedom of information, free speech and patients’ rights to information; and at the same time, EU officialdom either condemns or

⁷³ Draft report, p. 17.

remains highly suspicious of advertising, not only for medicines but in general.⁷⁴ In other words, freedom of information is seen as beneficial to the extent that it is supervised by government (and in the case of medicines, by general practitioners), without undue interference from the primary constituency, health consumers.

But empirical evidence suggests otherwise: the patient is no longer content with being the understudy of the play. Increasingly aware of alternatives, she is demanding to be better informed about existing options and actively seeking information on her own. Advertising is an important part of this process and but one source of information among many others, in any context. Consumer research has integrated this wisdom, and few manufacturers today (of any good) believe that consumers will decide to purchase a product solely on the basis of viewing information contained in advertisements.

Yet advertising is often vilified as a means of manipulating consumers into buying products and services which they don't need or even want. As shown by surveys, this is clearly an exaggeration which distorts the nature of advertising. Conversely, as suggested by one report "improved information generally brings in its train greater competition, better services and lower average prices without in any way diminishing professional standards, as long as misleading advertising is properly controlled by legislative or self-regulatory systems".⁷⁵

Advertising: An Essential Tool for Knowledge about New Products

Why is advertising important? Broadly, communication, marketing and advertising are information tools which are an integral part of the production process. A new product may not achieve the status of economic good (be it an apple, an aircraft or a medicine) without consumers being aware of its existence. In other words, a product cannot exist in the marketplace unless the producer is allowed to advertise it. This is why entrepreneurs invest in advertising and marketing. In this sense, information in the form of advertising is an essential factor of production for any given good, including medicine. Therefore, it is not enough if a new product has been manufactured, or that it is clearly needed; if nobody knows about it, it is useless.

If we agree that the market is a place of constant discovery, where information is scarce (and has a price), then both consumers and producers must be entrepreneurs in discovering the unknown. As remarked by the Austrian economist Israel M. Kirzner:

"In order to serve the preferences of consumers, producers have to do far more than merely fabricate and make available the goods they believe consumers desire most urgently. They must do more, even, than to make available the information they believe consumers need to acquire and appreciate the goods on offer. After all, the

⁷⁴ It is worth noting that the World Federation of Advertisers supports the status quo on pharmaceutical advertising (cf. <http://www.wfanet.org/news/copy.asp?id=1609>).

⁷⁵ "The advertising of pharmaceuticals direct to consumers: a critical review of the literature and debate", F. Auton, University of Westminster and Autonomy Consulting Ltd (International Journal of Advertising 23, 2004)

entrepreneurial discovery perspective shows that mere availability does not guarantee that those needing information will have it. Even if information is staring them in the face they may simply not notice it, and remain unaware that there is anything further to be known.

It is therefore necessary for producers, intent on winning the profits from innovatively serving consumer preferences, also to *alert consumers* to the availability and the qualities of goods. Clearly there is a role for advertising beyond providing information in response to consumer demands.”⁷⁶

Firms manufacturing new products don't invest in advertising just because they enjoy seeing their latest innovation highlighted in the media. They seek to alert consumers of something new which might satisfy their needs. The American National Consumers League (NCL) surveyed its members in 2003: “With DTC ads, large numbers of consumers are made aware of medical conditions and treatments that they may otherwise not know exist”, according to NCL president Linda Golodner. “But they are smart; most recognise that ads are tools for selling products and evaluate them accordingly.”⁷⁷

Cost or Benefit?

But advertising and other forms of patient information will remain useless if they are disconnected from the product in question, just as a certain active ingredient, such as paracetamol, has no particular value apart from being an essential component of a painkiller. Advertising is a complementary factor in the production of a medicine, as is any component in the production process.

Opponents to advertising, however, claim that advertising carries a cost which will be added to the other factors of production, thus increasing the price of the final product. In reality, any entrepreneur will spend money on advertising, not because this has a value in itself, but because the product offered has a potential value for the consumer.

More importantly however, information as a factor of production needs to be produced. Health care consumers in the European Union today may indeed find some information about new treatments and products despite the advertising ban (notably through consumer magazines and the Internet). But to get their hands on new products, they still depend on their doctor, since the latter retains a virtual monopoly on specific patient information. According to anecdotal evidence, the most important change in the past decade in the patient-doctor relationship is that patients increasingly bring their own information on their ailments along to the appointment. Finding health information is one of the major reasons, perhaps even the first reason, for using the Internet according to surveys. Leaving aside the relative value of the data thus gathered, this should be taken into account when discussing freedom of access to information.

⁷⁶ I.M. Kirzner, *How Markets Work : Disequilibrium, Entrepreneurship and Discovery* (London : Institute of Economic Affairs, 1997), p. 54. Cited in Mingardi and Stagnaro, p. 4.

⁷⁷ Cited in Saunders, p. 27.

In other words, the EU legislation still leaves the general practitioner in charge of direct and product specific consumer information, whereas a free market in product advertising would simultaneously let the patient access more information on a competitive basis and give her greater clout in discussing new treatments with her doctor. The EU ban on advertising prescription drugs is a major obstacle to such a development, however. Indeed, the restriction on advertising effectively prevents information from reaching the desperately ill in some cases, whereas cures do exist in other countries.⁷⁸

Following the accountant logic of cash-strapped Welfare States in the EU and elsewhere, health expenditure is a prime target for savings, in particular medicines. Opponents to DTC advertising often cite the growth in spending on new drugs as evidence of useless marketing with little or no therapeutic benefit.⁷⁹ In other words, it is often a case of “damned if you do, damned if you don’t.” If consumption of new drugs increases, this is seen as evidence of the negative impact of advertising; if it doesn’t, then advertising may be condemned for that reason. Another major argument is that, although patients evidently request more and better information, this demand had better be satisfied by public organisations with political support, on EU or national levels.⁸⁰

DTCA: The New Wave

In the United States, we may observe a very different trend and a surge in demand for approvals of a new generation of DTC advertisements (cf. p. 8). Some actors are even using the term “aducation” to describe this new wave of mass-marketing designed to better inform consumers. Whereas safety concerns remain central, there seems to be more innovative ways of communicating with patients beyond stressing the potential risks of a product. As one commentator wrote: “Research doesn’t support the idea that risks and benefits should be fully communicated in broadcast ads. And expecting patients to become experts simply by viewing a commercial doesn’t make a lot of sense.” But on the other hand “the most profound effect of DTC isn’t consumers’ knowledge about a single drug. Rather, it’s what they think about medicines in general”.⁸¹

Similarly the Coalition for Healthcare Communications filed a citizen petition in March 2006 on DTCA “to make consumer advertising simpler and clearer, and to stimulate better dialogue between patients and physicians”. Also, DTCA should remind consumers that “all drugs have potential risks as well as benefits. That prescription drugs can only be described by physicians. That the decision to take a drug should involve a discussion of risks with the physician. And that patients should fully discuss their conditions, medical histories and medications with their doctors”.⁸² In short, rather than getting bogged down in the details of the brief summary for television ads, we should remember that consumer advertising is for consumers. The discussion has devoted considerable time to the “fair

⁷⁸ E.g. new cancer drugs (cf. “Access to cancer drugs unequal across Europe”, Reuters, 6 Oct 2005).

⁷⁹ Cf. Health Action International Europe : Symposium Report, 2002.

⁸⁰ One recent initiative is the EU Health Portal, launched in May 2006 :

⁸¹ “Step One”, Pharmaceutical Executive, January 2006, p. 98.

⁸² “Regulation : A risky business”, MM&M, May 2006, p. 8.

balance“ requirement: but advertising is essentially not about fair balance, nor do consumers expect it to be, as numerous surveys have shown.

Nevertheless, there seems to be some room for more general and unbranded medical information, especially for underdiagnosed conditions such as diabetes.⁸³ According to one advertising executive, “pharma companies and their brands have an unprecedented opportunity to become the go-to sources of information on diseases and disease management and to play a major role in increasing consumers’ healthcare I.Q.”⁸⁴

In comparing US practices with the negative EU perspectives for DTC advertising, it is interesting to note that requests for branded products are made at the same rate on both sides of the Atlantic, according to a 2003 survey covering 53,000 people in the US, Germany, the UK and France.⁸⁵ This raises the issue of DTCA effectiveness; but it is not yet clear at which level and what conclusions to draw from these results.

Getting It Online

Perhaps the most contradictory aspect of the Internet age is the profusion of health websites. This also enables Internet users residing outside the USA or New Zealand to access prescription drug advertising, both push and pull. In addition, health information is the number one search object on the Internet.

But as one critical publication puts it: “Online health information can harm as well as heal.” This is of special concern when dealing with so-called complementary and alternative medicines which are sold without prescription. A survey was carried out in 2004 by the Journal of Medical Internet Research on the three most common herbal remedies (in terms of dollars spent): ginseng, ginkgo and St. John’s wort. It concludes that 38 sites (25% of the sample) contained information which could cause direct harm if implemented and 145 sites (97%) had omitted vital information.⁸⁶

At the same time, while providing easy access for patients and a host of additional data for many diseases, it remains true that practically anybody can start a website and fill it with insufficient or erroneous product information or even deliberate lies about existing medicines. The only ones to be prevented from communicating on the web about medicines are the manufacturers of those products. Moreover, they cannot respond to accusations or false claims, nor even provide factual information.

⁸³ According to the Coalition for Healthcare Communication, approximately one third of Americans suffering from diabetes were undiagnosed. Diabetes costs \$ 98 billion per year in medical costs and lost productivity in the United States (Auton, p. 34).

⁸⁴ T. Lom, president, Saatchi & Saatchi Consumer Healthcare, MM&M, December 2005, p. 22.

⁸⁵ 2003 National Health and Wellness Survey, conducted by Consumer Health Sciences. Source : MM&M, November 2003, p. 30.

⁸⁶ “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, 6, 2004 (<http://www.jmir.org/2004/2/e21/>).

III – DTCA: Review and Critique

As discussed in the previous sections, critics of DTC advertising predominantly proceed from a basic, yet mostly implicit, assumption: patients as consumers are vulnerable and/or incapable of correctly absorbing and evaluating medical information as opposed to promotional messages (again assuming that a clear distinction between the two is possible).

The problem with this approach is its aprioristic nature: admittedly, there is always room for improvement in any given field of experimenting the effectiveness of competing information sources, be it for choosing a doctor, a school or even a pair of shoes. But any progress implies that this competitive process be allowed to develop. This remains true for any human activity based on trial and error that includes mistakes on all sides, even serious mishaps. But the alternative – prohibiting certain information sources – entails other costs and risks, the outcome of which is largely unknown.

Hence, we may justifiably question the grounds of the prohibitionists, as their stance is nominally based on speaking from a “neutral” position (i.e. as representatives of government or health authorities, devoid of commercial interests). Yet, how is objectivity defined in these matters? The reasons for which an individual seeks treatment are inherently subjective since the motives are based on intimate information linked to a particular disease-related context. Therefore, the power struggle implicit in the objection to advertising from government officials or researchers cannot be said to be a more objective argument than any other consideration.

While legal and regulatory constraints are part of the equation, the final issue remains the patient’s options in terms of dealing with a health problem, and the demands for information which this entails. Apart from policy concerns (public health budget trade-offs), this is what should form the main issue in any productive discussion on advanced health care.

We may identify several stakeholders (or lobbies) involved in this pursuit: patients, physicians, industry, government and related secondary interest groups. Given the politicization of health care, the outcome of this struggle will necessarily reflect the relative influence in public policy spheres of these actors. But it is not forcibly conducive to patient empowerment, since many participants are vying for power regardless of their status in terms of patient interest. Hence, statements from government sources cannot *per se* be considered more objective than others; merely as a reflection of power politics.

Myths and Fallacies

The following is a review of the most frequent responses to advocates of DTC advertising advanced by critics.

“Drug advertising pushes up prices.” According to this argument, advertising costs are passed on to the consumer, demonstrating its modest utility. Also, advertising would have little to do with the quality of the product. This however disregards the link between the product, the consumer need and the value of information. As explained by the Austrian economist Ludwig von Mises:

“The costs incurred by advertising are (...) a part of the total bill of production costs. A businessman expends money for advertising if and as far that the increase in sales resulting will increase the total net proceeds. (...) In increasing production costs per unit, the idea is always to increase demand. If a businessman wants to increase supply, he must increase the total cost of production, which often results in lowering production costs per unit.”⁸⁷

In other words, advertising is justified to make a product known on the market, and the costs will decrease to the extent that production increases because the product encounters consumer demand and success on the market. Similarly, advertising would not take place if it were a net cost to the producer: it is an investment expected to generate profits, encouraging higher expenditure on research and development.

“Drugs are not like other products”. In fact, drugs are exactly like other products to the extent that they are produced to satisfy a given demand. We may only claim that a product is specific because it fulfills a particular need (transport, food, childcare, etc). But this applies to all products and services. Of course, all services are different: we do not expect the same outcome from medicines as we do from a plumber, a greengrocer or a car mechanic. But we still expect to have our demand satisfied.

“Drugs are dangerous.” This is true; but again it is an argument which could be used for banning advertising for almost any product which is handled and consumed without proper concern for consumer information and advice. To use an analogy, automobiles are highly dangerous and expensive products. Purchasing a car involves extensive cost/benefit analysis for the consumer, including safety features, since this is literally an issue of life and death in many cases. But the fact that automobiles and their use carry inherent risks is not a valid argument against advertising.

“DTC advertising puts pressure on doctors to prescribe.” As we have seen both in the US and New Zealand experiences, physicians are divided on the effect of DTCA. But the “pressure” often invoked does not concern a push to get a specific product “seen on television”; it is the *time pressure* felt in responding to the patient’s questions. As practitioners are often paid a set and regulated fee per patient, extensive Q & A may not

⁸⁷ L. von Mises, *Human Action*, chapter XV, p. 230. Source: Library of Economics and Liberty (<http://www.econlib.org>)

necessarily be their first priority. A certain portion of physicians also resent informed patients because this implicitly questions their professional authority and reputation; but this is a different issue.

“New drugs are not really new; therefore advertising is an unnecessary expense.” The supposed lack of innovation means that new products bring few if any therapeutic benefits compared to older medicines.⁸⁸ The logical question is then: how old should products be? Should government proclaim that development of medicines has now reached an optimum? The author has worn glasses since age 8; does it mean that he should be content with this, and not undergo surgery, because government administrators have decided that laser operations bring no tangible benefits relative to costs? Who is short-sighted in this context? This is probably not the type of outcome intended by critics; but it highlights the lingering belief in the virtues of government regulation of supply and demand in the health care market.

The following text was recently released by a European government:

“Political parties are spending considerable amounts of money on promoting their programmes. These campaigns are conducted regularly and the costs are spiralling. Yet there is little evidence that new candidates and policy proposals bring additional benefits to voters in terms of better politics. Older candidates and policies have frequently been found to be just as effective and less expensive. Having reviewed expert advice (a specialist committee composed of MPs, local councillors, mayors and pollsters) Parliament has voted to prohibit political direct-to-voter (DTV) advertising (including print media, billboard, television and radio advertisements). Such advertising has proven to be biased towards new ideas, without due concern for the risks which voters are exposed to. Extensive pre-election testing in laboratory conditions by political scientists, sociologists and psychologists is deemed insufficient as proof of the innocuous character of advertising new programmes and candidates.”

Obviously, this text is imaginary; but it may be replaced it in the context of DTC advertising to better appreciate the logic of current legislation.

*“Advertising downplays safety.”*⁸⁹ Producers are frequently accused of stressing benefits and minimising or even omitting the risks involved which is cited as an argument for strict government regulation of advertising practices.

In fact, there is no direct link between additional clinical trials and safer medicines. The length of the FDA approval process for new medicines has doubled since the 1960s; the financial costs have doubled since the late 1980s. Moreover, the number of clinical trials for each new product doubled from 1977 to 1995, and the number of patients involved tripled.⁹⁰ According to a 2004 study, the net social cost of healthcare regulations amount

⁸⁸ Cf. “Direct-to-Consumer Advertising of Prescription Drugs : The Evidence Says No”, J. Lexchin and B. Mintzes, *Journal of Public Policy & Marketing*, Vol. 21, Fall 2002.

⁸⁹ “Drugs in the News”, A. Cassels et al., *Canadian Centre for Policy Alternatives*, April 2003 ; Gardner et al, “Direct-to-consumer prescription drug advertising in Canada : Permission by default ?”

⁹⁰ Cannon and Tanner, p. 121.

to \$169 bn. We may compare this to the amount spent in 2002 by Americans on petrol and oil (\$165.8 bn) or on pharmaceuticals (\$162.4 bn).⁹¹ Yet, over the past 40 years the percentage of medicines withdrawn because of dangerous side-effects has remained constant (about 2-3%), as pointed out by former FDA Associate Commissioner Peter Pitts. The major safety problem is the improper use of otherwise safe medicines such as OTC painkillers (e.g. aspirine and ibuprofen) which “cause thousands of hospitalizations and hundreds of deaths each year”.⁹²

The safety issue is in reality a major argument for continuing to develop information to patients. Despite a number of problems involving the content and design of advertising, surveys in the USA and New Zealand aimed at both patients and general practitioners have shown that DTC advertising is providing more information and improving communication between doctors and patients.⁹³ As more data accumulate thanks to a competitive market for health information, safety improves as well. Indeed, the market already takes care of improving safety through consumer surveys, websites and even independent product certification which for the US market has been shown to be more efficient than FDA procedures.⁹⁴

The current experience in developing more effective and informative advertising in the United States and New Zealand has yielded tangible benefits for patients, which would not have occurred with a ban on advertising. The reason is simply that less information and data on consumer behaviour and physicians’ response to DTC advertising would then have been available. In this sense, even negative results and reactions to advertising are useful, as are critical opinions in surveys. The data thus gathered may be used to improve safety regulations, professional consumer advice as well as GP practices. Hence, the safety concern benefits from a wider array of information sources; restricting or banning advertising is not a solution which would increase consumer influence.

Critics are numerous and raise valid points; but the criticism is confined to the current policy context. The counterargument relies on the basic premise that health care is (and ought to remain) a government concern. This implies that the increased demand for services (stemming in many cases from more and better information regarding available products and treatments) is essentially a burden on society and a threat to redistributive justice. Therefore, any incremental change to the existing setup may be considered a political problem, subject to collective bargaining.

This argument is coherent from a Welfare State perspective; moreover, the advocates are frequently at the service of these concerns with a legitimacy of their own. Still, they fail to appreciate the force of the paradigm shift taking place which is slowly allowing

⁹¹ Idem, p. 112.

⁹² “Streamlining drug approval”, R. Goldberg and P. Pitts, Washington Times, 22 June 2006.

⁹³ “Turning Point or Tipping Point : New FDA Draft Guidances and the Future of DTC Advertising”, P. Pitts, Health Affairs, 28 April 2004.

⁹⁴ “New Uses for Old Drugs”, in *Competitive Strategies in the Pharmaceutical Industry*, AEI, 1996 (cited in Cannon and Tanner, p. 123).

citizens to evolve into sovereign decision makers in terms of health care services, regardless of current government interest groups.

Admittedly, a full-fledged market for health services is far from being a reality; but consumers are already set to make the leap: since they have already paid the bill through taxes, often without getting the service expected, the quest for choice and value for money is set to continue. Therefore, the conflict is increasingly overt: what is at stake is not patient choice, but the recognition of the right to choose by the guardians of previously protected domains. Politicians and regulators may well ponder their alternatives; meanwhile, consumers are in hot pursuit of the best options.

Conclusion

As FDA Deputy Commissioner Dr. Janet Woodcock has remarked, when it comes to DTCA, “the genie is out of the bottle”. The issue of increased access to various information sources for health consumers is not going to disappear. Rather, it will evolve by fits and starts depending on several factors, the most important being the individual patients who are not ready to settle for traditional health care where the person treated is simply a component of an overall policy scheme.

In ancient Greece, the science of government and democracy was reserved for the free citizens, i.e. the “liberal arts”. Slaves could be taught other skills but were excluded from these higher concerns. Similarly, the discussion on the access to information needs to reach a superior level where health data and patient concerns have evolved to include all participants. Patients have been citizens all along; but being a citizen in a health care perspective is currently confined to influencing politicians, health care regulators and administrators. This paradigm is clearly a thing of the past in terms of health: today’s patients demand to be treated as customers who require speedy access to services and new treatments, regardless of borders and national budgets. And if need be, surveys indicate a readiness to pay out-of-pocket. Serious reform must integrate the freedom of information for all actors.

This transition is far from being accomplished, as public health systems remain more concerned with budget constraints than attentive to consumer demand. Therefore, the consumer revolution will increasingly depend on patients voting with their feet through health tourism, than on political reform agendas which are inert by nature. This pressure will be brought to bear on existing systems through market forces, as consumers thanks to improved information progressively opt out of national services by seeking treatments elsewhere. This is true in the United States and the European Union alike.

The globalisation of markets is set to define health care in the coming decades, since consumers are becoming well aware of existing options, nationally and internationally. Only comprehensive market reform of national health care systems which takes this trend into account may alleviate the burden on taxpayers who pay for services which are often inadequate in terms of quality, and too expensive compared to alternatives.

Therefore the DTCA experience deserves support on the basis of belief in consumer sovereignty, where the individual faces a multitude of options in health care products and services. Recent consumer research corroborates this fundamental postulate, without which no social science is possible. The issue is not whether “homo oeconomicus” is constantly maximising his profits; but whether individuals are capable of understanding their environment and making the best out of existing options, based on limited information and scarce resources. It is not about a fictitious society with perfect information and no transaction costs; simply about individuals seeking the best possible knowledge to satisfy their needs. Regulation remains an inescapable part of this framework; but the essential component providing a dynamic is the freedom to pursue knowledge through individual choice.

The issue of patient information including consumer advertising is a major element of this debate; and no attempt to restrict the access to information will change this. Health consumerism is a tidal wave: its first casualties will be those who resist change to protect their entitlements. The beneficiaries are countless; and they are increasingly determined to challenge the status quo.

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About CMPI

The Mission of CMPI is to discuss, debate and demonstrate how exponential and accelerating technological progress coupled with smart public policy will enhance and advance 21st Century health care by predicting, preventing, diagnosing, and treating diseases with greater speed, more precision and less cost. Peter Pitts, former Associate Commissioner of the United States Food and Drug Administration, and Dr. Robert Goldberg, a leading health care thought leader and former Senior Fellow at the Manhattan Institute, founded CMPI for Policy Research.

About DrugWonks

Drugwonks.com is the web log of the Center for Medicine in the Public Interest (CMPI), a forum offering rigorous and compelling research on the most critical issues affecting current drug policy.