

Unlocking Ideas

Essays from the Amigo Society

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Essays from the Amigo Society

Arne Björnberg, Manuel Campolini, Pat Cox, Brian Crowley, Duncan Curley, Johan Hjertqvist, Pavel Hrobon, Johnny Munkhammar, Peter Pitts, Jan Remans, Anders Sandberg

Introduction by Jacob Arfwedson

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SOCIETY

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Introduction

Jacob Arfwedson

The Amigo Society was founded by the Stockholm Network in October 2004 to provide a forum for policy debate on Belgian social and economic reform.

From the outset, the aim was to include a wide range of participants, including policy makers, civil society representatives, think tanks, entrepreneurs and the media. Although the primary focus is on the Belgian discussion, we quickly realised that almost any issue today, especially in Brussels, must incorporate the European perspective. This collection of contributions to the Amigo Society over the past two years therefore includes the views of other Europeans and prominent EU representatives who have a major stake in policy reform in the enlarged Union.

Ironically, the Hotel Amigo was once the site of a prison, where the most famous inmate was Karl Marx. We thought it an interesting twist to make this the location to offer an antidote by unlocking ideas for the 'spectre' of reform now haunting Europe.

The authors encompass a wide spectrum of expertise and write from diverse backgrounds. While every country is unique,

the essays highlight universal values of consumer choice and market mechanisms in government reform which may be adopted in and adapted to any national context.

Section One deals with health and welfare reform in a pan-European context, including a comparison with Canada. Section Two examines the biotech revolution, and looks at its possible impact on future healthcare, an influence which is often overlooked in a static context of redistribution and budget cuts. Finally, we discuss consumer empowerment as a reform tool in formerly closed health services, and the issue of intellectual property and competition policies, which form the framework around which the healthcare market of tomorrow will be developed.

The enlarged EU offers a large array of policy reform experiences. Brussels is an exciting and competitive venue in which to bring these lessons to the debating chamber. The following is a cross-section of opinions and analyses which are set to shape the European debate in the near future.

part 1

Health and welfare reform

1

Hope comes from the east

Johnny Munkhammar

'Is Europe doomed?' My reply is: definitely not. Europe has a great future. But the European Social Model is bound to fail. We must make fundamental economic reforms now to save us from this sinister fate.

There is a feeling in society that we are heading in the wrong direction, and that we are turning our backs on a happier past. This is especially true of those who desperately want to hold on to the European Social Model. This reminds me of the 'Stockholm syndrome', when hostages become sympathetic to their captors.

In contrast to many people in Sweden and Britain, I consider myself European. I believe in Europe and I have worked hard to get my country more involved in the European Union. Every single principle of freedom that I have worked for has its historic roots in Europe, from the Enlightenment to the growth of capitalism. Our continent has a great heritage of freedom – and we must build on that.

In the last 60 years, Europe has experienced very positive

development. There has been peace and democracy in western Europe for a longer period than ever before. Since 1989, almost every country on the continent operates on principles of human rights and democracy. There has also been economic progress. Of course, the European countries that were destroyed after the war are now more prosperous. In the 1950s and 1960s, growth was high. The single market has indeed been a very important positive development in the subsequent decades.

But western Europe has made one fundamental mistake: we created the so-called European Social Model. Its aim was said to be to improve people's living standards and welfare, but the results have been the opposite. We got low growth, high unemployment, mediocre welfare services and many people living off the state. Today, unemployment stands at its highest in Germany for 75 years. In Sweden, only 3 million out of a population of 9 million go to work on an average working day and public health waiting lists are dangerously long.

As a result, western European countries are starting to make reforms. They have different names, and the most famous is probably Agenda 2010 in Germany. But they all have the same objectives of reducing government involvement, lowering taxes, lowering money transfers from the state and developing competition in welfare services. So far, the reforms have just scratched the surface. But globalisation offers new challenges and governments realise that they have to diminish their involvement.

What is the European Social Model?

The European Social Model is based on high tax burdens

financing state-owned monopoly welfare services. At one end of the spectrum lies Britain, with a tax burden of 39%, and at the other end is Sweden, with 51% – the rest of the western European countries lie in between. In continental western European countries, however, there is a tradition of private, albeit tax-financed, welfare services, whereas in the Nordic countries and Britain they are provided by public monopolies.

Across Europe, tax burdens have risen dramatically, from about 20% in 1950 to 40–50% in 1980. Government finances and provides welfare services such as education, healthcare and old-age care. In various forms, the model also embraces systems for social security, with public pensions and income transfers for unemployment or disability. The labour market is also highly regulated or arranged in a corporatist way.

This model emerged in a post-war Europe and aimed to improve public welfare. But there were other factors involved:

- At the time, it was commonly agreed that a centrally controlled economy was preferable to other alternatives.
- In order to win elections, politicians promised their citizens more benefits, which inevitably led to a rise in taxation. Ultimately, only government benefited from this vicious trend.

An even closer state?

The core principle was that there should be only one provider of welfare services and social security: the state. There would not be any private companies, private property, free competition or free financing, even though these are the very forces

of development. Does anyone think that we would have all the innovation in mobile phones with a single state telephone monopoly? What kinds of food and drink would we have if they were not produced and delivered by private companies? Lines of people queuing to buy bread, most likely. And we can observe the equivalent situation now in healthcare.

This model is based largely on the assumption that there are resources just waiting to be shared by everyone. There is a big cake which government can simply distribute to people. That is a fundamentally false assumption. All resources have to be created; there is no car, no hospital, no heating for your house, existing in 'nature'. We need to create a society with the best opportunities for resource creation. The European Social Model does the opposite.

Waiting for Lisbon

One of the issues behind the Lisbon Agenda, which was created in 2000 to improve European competitiveness by 2010, was the wealth gap in comparison with the USA. Since the Lisbon process was announced, however, the gap has widened further. In fact, the average person in 38 American states is richer than the average person in any country in Europe, except Luxembourg, and the average American is about 40% richer than his or her European counterpart.

Employment there is also higher: between 1970 and 2003, the number of employed in the USA rose by 58.9 million, a 75% increase. In France, Germany and Italy together it rose by 17.6 million people, or 26%.

High taxes and high levels of social protection have created

a situation in western Europe where few work and more people live off the state. That makes the Lisbon Agenda aim of increasing the employment rate to 67% of the working-age population somewhat pointless, since that share of the total population continuously decreases.

Globalisation increases competition and mobility, which pushes taxes downwards. Companies will place their production where the conditions are best. Larger Swedish companies have outsourced jobs in recent years. Taxes on capital and corporations have already been lowered and this will continue.

Yet the Wim Kok Report, *Facing the Challenge*, states that 'to achieve the goals of higher growth and increased employment in order to sustain Europe's social model, will require powerful, committed and convincing political leadership'.

A challenged model

If we look ahead, we can see that the main tenets of the model will be challenged by reality:

- 1 When public pensions were introduced in Sweden, the pension age was 67 and life expectancy 55. Today the real pension age is 58 and life expectancy is 80. So we had to embark on pensions reform. Unfortunately, it only got halfway. Under the current systems, the working-age population in Germany would be reduced from 56 million today to 41.5 million in 2050. In Italy, it would decrease from 39 million to 22 million. Expenses would skyrocket. In Spain, the public pensions share of total public expenses would increase from 50% today to 80% by 2030. We have to reform public pensions, perhaps by abolishing the pension age.

- 2 Other European countries have similar systems of mandatory public benefits for sick leave, unemployment, parenthood leave and early retirement. In Sweden, there are in practice no limits to how long one may live off these benefits. The basic public level of contribution is 80% of salary, but most people enjoy higher levels owing to negotiated extra benefits. On an average income, the benefit from going to work instead of living off these systems is about €5–10 a day owing to the high taxes on labour. Thus, many people choose not to work. Only about 3 million out of the Swedish population of 9 million go to work on an average day. Over 60% of the adult population is to some extent dependent on the government. Lower taxes and lower government contributions are desperately needed.
- 3 In western Europe, the government finances most welfare services, including healthcare, child and elderly care, school and higher education. In many countries, the services are also almost entirely provided by government. Basically this is a planned economy based on government monopolies. The results are long waiting lists, inefficiency and wasted resources. People working in the public monopolies have low salaries, little influence and the emergence of a new service sector is impeded. Free competition in welfare services would create better services, freedom of choice and efficiency, and would nurture new ideas.
- 4 Western Europe has the highest taxes in the world. Naturally, this makes our climate for creative business and work less attractive in a global perspective. In Sweden, the

average wage per hour for a worker in industry is about €20; in China it is €1. This discrepancy is not matched by a difference in productivity, and taxes are of course one explanation for the difference. One in three Swedish companies has outsourced production in recent years. This is not a threat – growth in China, India, Brazil and elsewhere is good for the world – but it is a challenge for the West. Lower taxes would release the constraints on productive forces and make education and work more profitable, allowing new companies and jobs to emerge.

The model is fundamentally challenged. Big changes are needed, and they will come. And I think that hope comes from the east.

Growth in the east

The EU-25 area has an annual growth that is twice that of the EU-15. There is development, optimism, new jobs and improving living standards. Slovakia, for instance, has become the biggest car producer in the world relative to the size of the country.

These countries never joined the European Social Model – though some have come close to it. They were liberated from the planned economy and did not want it back in any form. These countries, by and large, have a limited state and a big civil society. In Hungary in 1992, the state accounted for 70% of the economy. Today it is 14%. They have limited regulations for companies and labour. The main feature is low taxes, especially the increasingly popular flat tax – in nine countries.

Everyone pays the same percentage in tax regardless of income – simple, fair, and work always pays.

Of course, competition from these countries is felt in the west. Austria lowered its corporate tax rates from 34% to 25%. Germany will decrease its rates from 25% to 19%. Countries are realising that a high tax level is no guarantee of high revenues. Slovakia generates 2.3% of GDP in corporate tax revenues from a 19% tax level. A large western European country may generate 0.7% of GDP from a corporate tax level twice as high.

Bumpy road, bright prospects

Europe will have a bright future: higher growth, more and better jobs, new companies, increased living standards. But that is after reform, when government is smaller and civil society larger. When we have created better conditions for those forces that create prosperity, society will become better off.

2

Getting the politics out of healthcare

Brian Crowley

Canadian Medicare operates essentially as an unregulated, tax-financed, pay-as-you-go monopoly.¹ Canada's provincial governments are the monopoly providers of healthcare. They not only pay for necessary care, but also govern, administer and evaluate the services they themselves provide. They define what constitutes 'medically necessary services' and then pay for virtually all such services provided in Canada. They forbid the provision of private insurance for these services. They negotiate payment schedules with the powerful provider groups. They often set the budgets for nominally private healthcare institutions, appoint the majority of their board members, and have the explicit or implicit power to override management decisions.

Anyone who doubts that provincial governments consider themselves the governing force behind the entire healthcare system failed to observe the election a few years ago in the province of Manitoba. In that campaign the quality of toast in hospitals was a major election issue, and it was clear that the

parties thought that they could and should be able to affect this matter, and the electorate thought that this was a credible claim.

Another powerful example occurred several years ago in Nova Scotia. The CEO of the local hospital was nominally an independent authority, but his budget came almost exclusively from the provincial government (the next-biggest source of revenue was parking fees). He had been given strict instructions that he was not to run up a deficit, and he had also become mired in a series of difficult labour negotiations. Eventually the premier of the province telephoned, telling him to settle the disputes. In those circumstances, no one can be expected to take any responsibility because decisions will always be second-guessed by those in political power. Therefore it is better to make them take responsibility up front by deferring to them rather than trying to act in a managerially rational way.

The final example of how politics and healthcare constitute a poisonous mix lies in the field of technology. In most industries, technological innovation is a cost reducer, not a cost driver, but this seems to be less the case in healthcare than elsewhere. This is driven by three key factors.

First, in many cases new technologies are not substitutes for existing techniques, but are additive – solving problems that we were unable to solve before, and yet not allowing us to dispense with already existing techniques and technologies.

Second, innovation only helps to reduce costs when you can shift activities from old approaches to new, more technology-intensive ones. But in the politicised system, these shifts of resources are severely hampered. For example, building a new hospital in a community may not lead to the closure of the old

one, not because the old one makes a significant contribution to the quality of healthcare, but because the government is not willing to take the political heat for closing the facility.

Finally, much of the system is driven by what governments are willing to pay for. If government is willing to pay for heart surgery, but drugs are paid for by consumers, then there will be tremendous pressure to keep heart surgery facilities and resistance to moving to drug-based therapies. This perfectly describes the situation in Canada.

In a competitive environment, consumers are free to ‘vote with their feet’. They did so in the 1970s, when they abandoned North American cars for Japanese imports, and again by preferring calculators to slide rules, natural gas and oil to coal, and faxes and e-mail to ‘snail mail’, even though in most cases the old dominant industry that was being abandoned was powerful, rich and well connected.

But in a monopoly the relative power of consumers and suppliers is completely reversed. Before the advent of competition in the telephone industry, dissatisfied customers faced the massive indifference of a bureaucracy that could take their business for granted. The telephone monopolies provided expensive and poor-quality service, and found myriad ways to punish customers who complained – even though politicians had a theoretical hand on the tiller through some quite powerful, if cumbersome, regulatory agencies.

Administrators of Canadian healthcare do not suffer direct consequences if they provide poor customer service. Nor are they answerable to a regulatory agency, other than the federal government’s unclear powers to withhold funding for violations of the equally unclear principles of the Canada Health

Act, in addition to the vague promises that emerged in 2004 from a meeting of Canada's prime minister and the provincial premiers. They all agreed to be more accountable for healthcare spending, but did nothing to make that promise effective.

Public sector monopolists face a conflict of interest: they are both the providers of a service as well as the people charged with evaluating the adequacy and quality of that service. By being both, these monopolists grant themselves the quiet life by the simple expedient of having virtually no hard measures of success and gathering almost no useful information about whether anybody gets better. As a colleague of mine likes to say, not a single healthcare institution in Canada can tell you whether anyone was made better, worse or was left unchanged by their contact with the healthcare system.

It is hard to tell how many people are waiting for health services, or how long they have been waiting. It is also hard to determine how many people manage to see a physician. Moreover, whilst 80% of the Canadian population live within 100 miles of the border, the numbers of those who are treated in the United States is unknown. One of the factors that have prevented the Canadian system from collapsing is the ease with which treatment can be obtained in exchange for money.

The final point on the USA–Canada comparison is that there is a lot of myth-making about how the US system works. The best summary of this was in a letter to the *Wall Street Journal* from a US doctor:

[The Canadian healthcare system] resembles the county hospital where I work. Our patients pay little or nothing. They wait three months for an elective MRI scan and a couple of months to get into a subspecialty clinic. Our

cancer patients fare better than the Canadians, getting radiotherapy within one to three weeks. The difference is that our patients are said to have no insurance (a term used interchangeably with 'no healthcare'), whereas Canadians have 'universal coverage'.

Dissatisfied Canadian healthcare consumers have little choice about dealing with the local health monopolist. Poor service, lengthening queues, high prices, inadequate technology – what's the alternative?

There is also a widespread belief that the healthcare system is 'underfunded', despite the fact that Canadians have never spent as much money on healthcare as today. One major reason is that every time fresh cash is injected, the monopoly providers, such as doctors and nurses, begin various kinds of job actions to capture that new money for themselves while giving nothing back in terms of increased productivity. Before the 2000 federal election, the federal government in Canada injected some \$20 billion into the healthcare system. The money disappeared without a trace. In 2004, Ottawa agreed to inject a similar amount. The chief effect will be to unleash a wave of job action throughout the healthcare system, and the queues will be just as long, and costs considerably higher, by the time the cash is all gone. All we will really have accomplished is to improve providers' incomes.

Unbundling functions

To inject the needed degree of competition, it is essential to unbundle the payment, administration, delivery and evaluation

functions. That government should ensure that no one goes without medically necessary services is not the same thing as saying that only government should provide those services.

The objective is to achieve *neutrality* on the part of governments when purchasing healthcare services from the public or private sector. If governments were truly neutral, they would not buy from *any* provider who could not meet tough accessibility, quality, price and accountability standards.

Strict reporting requirements would give government and the public an independent yardstick by which to measure the performance of healthcare institutions. And those institutions would have to provide better service, or else see their clientele leak away to competitors, and their valued employees decamp to better employers.

The informed patient

But the main objection from those who exercise political power is that patients do not know enough to be given this kind of authority to make decisions for themselves.

A few years ago, I asked Henry Haddad (then president of the Canadian Medical Association) to name the single most important way in which the practice of medicine had changed in the past decades. He said it was doubtless the number of people showing up in the doctor's office with print-outs from the Internet, containing information about their symptoms and possible diagnoses, but also a lot of information about alternative treatments. People are better informed and more demanding as consumers than ever before in the field of healthcare.

Virtually any kind of pharmaceutical product can now be purchased over the Internet from foreign providers who can evade governmental controls. Drugs can be purchased in on-line auctions and X-rays or MRI scans can be read just as easily by a radiologist in Boston or Bombay as in Toronto or Truro.

In 2004 the brain repair team at Dalhousie University in Halifax, Nova Scotia, operated on a patient in St John, New Brunswick. The surgeons never left Halifax. Using video cameras and computer controls, they operated robotic arms that actually did the surgery hundreds of kilometres away. When we can go to a surgical booth in Canada and be operated on by the best surgeon in the world, who may be in his office in London or Houston or Minneapolis, the notion of a closed national health system simply cannot survive.

The single-payer system

One objection frequently raised against creating an internal market such as I am describing is that the current system is hugely successful at controlling costs, and any lessening of the bureaucratic control would cause a loss of control of healthcare spending. This argument always makes me smile, for if people think that 5–6% increases in real spending per year represent 'cost control', I'd hate to see what they think constitutes out-of-control spending.

Until the introduction of Medicare (in the late 1960s), Canadian healthcare costs tracked those of the USA. Afterwards, Canada's growth in costs, and especially physician costs, dropped significantly after the predictable short-term rise. But people draw the wrong conclusion from that.

By the late 1970s, the two countries' expenditure growth series are back in synchronisation – in fact they were more closely aligned in that period than they were in any previous period. They diverge again only in the mid to late 1980s, when, arguably, Canadian governments became really serious about controlling spending.

In other words, it is not possible to identify a lasting effect of the introduction of Medicare on expenditure on physician services. The Canadian GDP share fell below the US figure, not because of differences in the rate of growth of expenditure but rather because Canada had the good fortune to bring in Medicare at a time when the Canadian economy outdid the US economy in real growth.

Interestingly, many Canadians are convinced that the difference in tax burdens between Canada and the USA is justified by the fact that we have universal tax-financed health insurance. The tax differential in 2004 was about 10–11 percentage points of GDP (30% as against 41%). Canada has the fourth-most expensive healthcare system in the world (worse if you adjust for the age of the population), and it spends 7% of GDP on publicly financed healthcare (we spend another 3% of GDP on privately provided healthcare). The USA, on the other hand, also spends 7% of GDP on publicly financed healthcare. Since the US economy is 20–30% larger per capita than Canada's, a point of GDP is worth a great deal more actual money. Publicly funded healthcare explains not one iota of the difference in taxation between Canada and the USA.

In addition, politically driven systems inevitably engage national pride in a way that is often destructive. It is surprising how many people fervently believe that their healthcare

system, despite its flaws, 'is possibly the best in the world'! Any talk of reform of our healthcare system is immediately met with cries of 'Americanisation!' As a good friend of mine likes to say, if it is true that Medicare defines the difference between Canada and the USA, then if the USA ever adopts the single-payer system, logically we either must abolish ours or cease to exist as a separate country!

Equally ironic is the fact that the Quebeckers have no such hang-ups and Quebec is in fact the province that as a result has been most open to experimentation and reform. It is now a province of private clinics. Quebec film-maker Denis Arcand was lionised by the left-wing elites in English Canada when his *Les Invasions Barbares* won the Academy Award for best foreign film. Fortunately, none of them speak French, or they would understand that the film is a root-and-branch attack on the Canadian healthcare system which they believe is the very foundation stone of their identity.

Conclusion

Canada is almost alone in the Western world in outlawing private access, through payment, to services that are also publicly insured. While we pay virtually the totality of physician services out of the public purse, many services, such as drugs or home care or long-term care, are not covered by Medicare, whereas they are insured in other countries. By denying people who wish to pay the ability to do so, we satisfy our ideological craving for egalitarianism, but at the cost of an inability to make room in the public budget for a wider range of services that low-income people might truly need.

This might be defensible if our system were superior to others. But neither the UN, nor the poor and the elderly in Canada, agree. When the WHO rated health systems around the world, Canada ranked 14th in 'overall system performance', among industrialised countries. Virtually every country ranked higher than Canada allows people access to health services through private payment, and many of them have as good or better population health indicators and spend more per capita on healthcare.

A Harvard study comparing the UN healthcare system rankings with the opinions of the population of each country found that Canadians' level of satisfaction with their system was 12th in the industrialised countries, again lagging behind a long list of countries with more formalised multi-tier access and a broader range of services covered by public insurance. The poor and the elderly in Canada both ranked her lower, at 14th.

Much of the debate about our healthcare system is ideological, and has little to do with the quality of care delivered. The small steps being taken towards more private provision of care within the publicly funded system are logical extensions of Medicare. The evidence from other countries is that such use of private facilities can introduce efficiencies and is certainly compatible with a dynamic and high-quality healthcare system in which no one is denied needed medical care on the basis of ability to pay.

The only way to ease the politics out of healthcare is by introducing competition and consumer choice, which, by its nature, transfers power to those whose decisions produce rewards for producers.

3

Eastern medicine for Western woes?

Pavel Hrobon

While medicine is changing rapidly, in terms of financing and organisation we are to a large extent stuck with century-old systems, be they Bismarckian social insurance or national health services.

At the time our systems were designed, healthcare was about saving lives and alleviating suffering. There was virtually no choice whether, where and which healthcare to consume. In other words, healthcare consumption was defined by need. Add to this very limited savings for most individuals and families and a positive demographic situation and you have all the reasons for introducing third-party financing (having the state or mutual health insurance funds pay for healthcare).

The current situation, however, is completely different. Healthcare remains in part about saving lives and alleviating suffering but is increasingly also about prolonging life and increasing its quality. There is a growing choice of providers and treatment methods. The financial situation of most people, especially if supported by widely available financial tools,

enables an average citizen to pay, not for all, but for a substantial range of health services. In other words, consumption of healthcare is more and more about choice.

Consequently, these outdated financing and delivery arrangements work pretty badly in the modern world. They reduce incentives to stay healthy and encourage over-consumption of health services while often denying real choice. They slow down innovation and decrease efficiency of the whole health service's provision systems. Growing dissatisfaction of citizens, constant deficits and new expensive technologies are not a future challenge, but daily routine for the people in charge of healthcare systems in European countries. All these problems will be aggravated by ageing populations.

There are only two sustainable ways forward: increase the efficiency of current health systems and engage people in decisions on health services consumption, all the while increasing understanding of the economic consequences of these decisions. All this has to be accompanied by funding mechanisms that are less sensitive to population ageing than the current pay-as-you-go systems and by preserving general access to basic healthcare.

In real terms, this means two things. First, the need to implement institutional reform, i.e. turning health services provision into a real market with payers acting as competing purchasers of care. Second, reform financing to encourage reasonable consumption of care.

Properly executed, these changes would turn current unsustainable provider-dominated systems into sustainable patient-centred ones without harming access to necessary care. Governments seem scared of such reforms, however, and prefer to defend the status quo.

Why central Europe?

What is the main reason behind the fact that some new member states of the European Union implement necessary reforms earlier than their more developed and experienced Western counterparts?

I do not intend to underestimate the personal contributions of all the bright and brave people who stood up for health reforms in Estonia, Slovakia and elsewhere. But such people do not appear only in those countries. How come they have succeeded there? We could have a long debate as to whether citizens in former communist countries are more or less used to extensive welfare systems, whether they have taken change as part of everyday life since 1989 or are actually tired of it.

The fact is that most eastern European countries have copied the generous welfare systems of the West, but cannot afford them. The individual irresponsibility these systems evoke, in combination with less efficient public institutions, is bringing our welfare systems, including health services, close to bankruptcy, even before population ageing kicks in. The bad financial situation is of course accompanied by real problems with access to care and its quality and consequently by a greater willingness to reform.

What is happening there?

The new EU member states from central Europe (Czech Republic, Hungary, Poland and Slovakia) look like a rather compact group in terms of history and GDP per capita. They have experience of the communist type of highly centralised and rationed national health systems. All of them also initiated substantial healthcare

reforms in the last decade of the twentieth century, which to a large extent copied statutory insurance systems in western Europe. A closer look, however, reveals significant differences in funding, organisation and recent developments of their respective healthcare systems.

The Czech Republic and Hungary spend per capita almost 60% more than Poland or Slovakia, measured by purchasing power parity. These relatively high levels of spending are nevertheless significantly lower than the average of 'old' EU member states. The share of public expenditure on health ranges from 70% in Hungary to over 90% in the Czech Republic. Despite these differences, all the new member states currently face a significant deficit in healthcare financing. The size of the deficit ranges from 42% of annual turnover of the system in Slovakia before the current reforms, to around 10% in the Czech Republic and Hungary.

The Czechs and the Slovaks rely on multiple competing payers while the Poles and Hungarians finance their providers through a single, albeit regionally organised, payer. On the delivery side the patterns range from highly centralised government-dominated systems in Poland and Hungary to a rather decentralised Czech system with a significant number of privately run hospitals.

There are also great differences in waiting times and access to modern technologies. Waiting lists are often unofficial and unmanaged, which favours under-the-table payments. The extent of the grey economy is of course hard to quantify, but indirect measures point to its significance and a negative correlation with the level of funding and competition in the system.

But – cannot we just increase the efficiency of current systems by some clever payment methods, planned allocation of resources or other management tools? In fact, increasing efficiency and offering patients more choice and efficiency are closely intertwined.

It is instructive to look at recent developments in the United States. While that country is probably not an example of a rational approach to healthcare funding, it is well ahead of Europe in terms of payer-provider arrangements. The last two decades have seen the so-called managed care revolution, which increased the efficiency of health provision and so moderated cost growth in the short term, but failed to do so in the long term. It also became hated by many patients and physicians alike because of the restrictions put on their choice.

Population ageing

In this context, the first impact of population ageing will make itself felt very soon, as the post-war generation starts to retire. In the long run, we expect the share of people over 65 years of age living in the Czech Republic to increase from 17% of the population today to 43% in 2050. We have modelled the impact of these changes on healthcare costs and the mandatory health insurance contributions. If we had the demographic structure of 2050 already today, the costs would jump by 30%. Combine this with the diminishing tax base, and the rate of health insurance contributions would have to more than double, from the current already high 13.5% of gross salary.

Practical reform steps

Health reform is a hot political issue in all these countries. So far, however, only Slovakia has started implementing real remedies. In Hungary and Poland reform was put on hold prior to 2006 elections.

The Slovak parliament adopted brand-new health legislation at the end of 2004. The extent and depth of changes made Slovakia a front-runner in market-oriented health reforms, not only among new member states but in the whole of Europe. The implemented changes include the introduction of user charges, an explicit definition of the basic benefit package covered by statutory health insurance, for-profit status of health insurers and providers, and selective purchasing of care by insurers. The reform has already led to a sharp reduction in the system's annual deficit.

The Czechs were moving away from real reform in the first half of 2006. The centre-left government, already at the end of its mandate, started a massive 'stealth' effort to move the Czech healthcare system towards a completely centralised NHS-like arrangement. Changes were pushed through without proper public discussion and led to the first real deterioration in access since the fall of communism, despite the fierce protests of physicians and patients' organisations.

The elections held in mid-2006 resulted in complete stalemate between the right and the left. This obviously means no room for real reform before the next elections, although these may come relatively soon. Meanwhile, the aim is to stabilise the current system and take the first steps towards a more sustainable system less dependent on government and politicians.

Real reform, changing the incentives of all parties involved in healthcare, will come sooner or later. There is no method of increasing efficiency other than competition between providers, and payers acting as purchasers of healthcare. This is what we call institutional or supply-side reform. It is necessary to:

- Change the legal status of health insurers and healthcare providers with the aim of defining clear roles and motivations, and improving transparency. To achieve this, it is necessary to turn most of them into standard for-profit institutions while keeping a complementary share of not-for-profit ones.
- Turn health insurers into real purchasers of care.

Finally, there is no other way to really engage consumers than to provide them with choice and responsibility for this choice. The responsibility also has to include partial economic responsibility, which is fully compatible with guaranteeing access to needed care to all citizens. Finance reform (demand side) includes the following main steps:

- Reducing the scope of mandatory insurance and defining the range of services covered. The current system pretends to cover everything. But if a patient needs elective surgery and waiting times can be up to two years, nobody is responsible for telling him when he may expect treatment and under what conditions. A patient with a myocardial condition might be treated with the latest technology or hospitalised without benefiting from the necessary technology, depending on which part of the country he lives in.

- ▶ Introducing individual health accounts in which public and private contributions would be combined to buy supplementary insurance or to pay directly for care not covered by mandatory insurance.
- ▶ Gradually turning individual health accounts into savings tools.

But whereas we want comprehensive reform, we also want to give people a soft landing. Those who do not want any changes should not notice much in the first years of reform. But those who want to make their own choices should be allowed to do so.

If we achieve this, what could be the value for the West? First of all, practical experiences of reform. Obviously, not all will work as planned. The challenges and principal solutions are very similar for all European countries. Second, we would dispel some of the myths that are today widespread in healthcare, such as the assertion that profits and provision of good patient care are incompatible, and there is no space for markets in healthcare. Last but not least, we would demonstrate that substantial reforms can be achieved, even in healthcare, which has long been treated as a sacred cow.

4

Reform and transformation

Pat Cox

As regards the Constitutional Treaty after the French and Dutch rejection, this is not the moment for pretence. It is not possible or advisable to carry on as though nothing has happened. Something profound has happened and we need to take stock of that, and not simply press ahead. I hope it will not be the moment for a self-consuming orgy of European introspection. One of the great benefits of the Constitutional Treaty was its attempt to draw a line under a lengthy period of such introspection. Europe needs to move on towards issues of delivery and performance in other domains.

If you are in a position of leadership in any organisation, and especially in terms of politics, you have a limited stock of capital with which to play. If you spend it all on introspection, you cannot spend it on other worthy, but potentially ignored, issues.

Nor is it the moment to engage in knee-jerk policy analysis and response. I hope that what will emerge from the EU summit with regard to the constitutional exercise will be an

appreciation of the necessity for a period of calm and deliberate reflection, not jumping breathlessly to ‘What next? What form? What content? What structure?’ Europe could benefit from such calm reflection.

I remain a strong enthusiast for the enlargement of 2004. It was a political imperative and economically advantageous for all the players involved (although not necessarily for every single individual and sector). It will remain a win-win situation for all contracting parties.

Impressive feats in new Europe

I marvel at the double transformation of the economies in central and eastern Europe, from communist command economies to market and pluralist democracies, and beyond that their transformation to accommodate the *acquis communautaire*. When I had the privilege of leading the European Parliament, I remarked many times when I spoke with parliamentarians of the new member states that I hoped one gift they would bring us as old members would be to remind us of and return to us our appetite for their reform, as well as their appetite for our reform.

We demanded of them degrees of social, economic and structural transformation on a scale that is difficult to imagine in western Europe, and on a basis on which we have hardly scratched the surface in comparative terms. Therefore they should not ‘shut up’ but should speak out with determination and self-interest, with a sense that they have something real to contribute to the politics of a wider European transformation.

Like the European Union itself, as we have witnessed in

recent campaigns, the enlargement project was poorly sold and badly communicated. It has ended up largely being characterised in rather negative terms. It seems to me that, without the Polish plumber and his Latvian, Lithuanian, Estonian, Czech and Hungarian friends in the labour force, our growth rate today and tomorrow would be severely diminished. The lesson is not that we should send the plumber home, but rather ask him whether he has a friend who could make an economic contribution to our ageing societies.

The freedom paradigm has manifested itself in a powerful and positive way in the new states. Consider a few figures:

In 1950, Poland had the same income per capita as Spain; in 1990 Polish income per capita was 40% of Spain’s (and the latter was at the time not among the richest EU states). Today Poland’s GDP per capita is more than 40% greater in real terms than in 1989. And this is true (although with lesser percentages) for all the states in central and eastern Europe, which transformed themselves, buying into the new freedoms and deploying them in terms of public policy, and which took encouragement and incentive from their European vocation to stick with the path of reform through thick and thin.

Compare this with former Soviet states that did not experience this transformation. Income per head in Moldova is 60% less than in 1989; in Ukraine it is more than 50% less and in Russia 35% less. We should not get too carried away with GDP figures and the grey economy, but they are indicative of real trends: the transformers who opted for the freer model are getting real, positive returns. The slow and non-transformers are carrying real handicaps.

Consider life expectancy: during the past decade it has

increased in Poland, from the early to the mid-70s. In Ukraine it fell from 70 to 68 years. The same is true for the data on infant mortality and energy use (energy coefficient per unit of GDP). Environmental and demographic data are all showing the same direction in trends, indicating that those who opted for transformation are reaping real benefits. This is evident in the growth of labour productivity, where transformers are up and the others are stagnant. This in turn has induced greater flows of foreign direct investment to the transformers than to the others.

Of course, not everything in the garden is rosy. But the performance is real in terms of rate of return and commitment to reform and transformation. It has left in its wake a diverse array of individual winners and losers: an interesting phenomenon of a relatively settled process of economic development, but a far less settled process in terms of politics. This is not the case in all states, but in many cases politics remains inversely settled in terms of predictive trends.

Slow going in old Europe

Consider the EU as constituted prior to 1 May 2004. In broad terms, the EU periphery (including the new member states) is outperforming the EU core. In even broader terms, there has been more willingness to transform and reform in the periphery than in the core continental economies. This has yielded much better than average rates of return in growth, labour productivity and employment, and lower unemployment rates, which demonstrates the direct linkage between more reform and better performance.

In the core economies – France, Germany and Italy, which account for slightly more than 70% of the Eurozone GDP – we continue to see economic stagnation. They have begun reform, with a mixed record and great political difficulty.

Even among these countries, there is differentiation. The German *Mittelstand*, with its dynamic private sector activity, was in 2004 the world's leading exporter in spite of the generally stagnant state of the German economy. Not all is black and bleak. But even within the stagnant economies, the different dimensions of demand (consumer demand, low savings, high exports) improved for Germany, a positive outcome from which the country will benefit in the future.

Looking at France, the performance of the companies on the CAC-40 index is very creditable, unlike the general and sluggish performance of the overall French economy. The Italian case is structurally different, with declines in productivity and sectors of comparative advantage and specialisation, more vulnerable to other global trends.

These examples all share one characteristic: the trade sector is in general terms producing a positive and significant contribution.

Blaming others

The French case is very interesting, because to a large extent the debate about the treaty – to my outsider's eye on my occasional visits to lend my forlorn assistance to the 'yes' campaign – was dominated by the conservative and non-trade sectors in France. These are more concerned with the *droits acquis* (acquired rights). The dynamics of the trade sector, as well as the political

impulse, are excluded: the needs of the unemployed are not alluded to by those who wish to protect the cosy comforts they already enjoy. The debate and its result run the risk in France of a further postponement of coming to grips with global realities, and the risk of encouraging throughout Europe a diminution of the required debate and structural change. I hope this is a risk that will be resisted rather than accommodated.

I found the extent to which *les autres* were always to blame very interesting: too often in Europe we leave market realities at the door when we make decisions. I find it hard to distinguish the ultra-liberal substance from the polemics of the debate. If it wasn't *ultralibéralisme* it was the *cousins anglo-saxons* or *les Américains*, or *la Turquie* or *Bruxelles* or *l'élargissement*, or, finally, *le plombier polonais*. Each of these was 'the other'; almost no debate was about the self. Such debate as there was about the self was about the natural superiority of the social model, a dimension of civilisation that should be accommodated by other Europeans. I have a problem with a model of civilisation that constantly condemns 10% of the population to the scrapheap of unemployment, and 20% or more of under-25s to the same kind of fate.

This is the debate that has to be entered. Where is the superiority of such a high level of unplanned but consequential obsolescence for so many people who, in other circumstances, would be willing to engage? What has come out of the French debate in particular, and of the Dutch referendum result, is a cautious conservatism, fearful of and resistant to change. Our continent, or our Union, is not at a juncture where cautious conservatism is an option.

The road to innovation

Let us recall some achievements outside the box of cautious conservatism. First, the liberalisation of the telecoms market: if Europe hadn't travelled down this road, some of the developments in terms of consumer benefits would have been delayed, at a severe competitive cost to Europe. Second, air transport liberalisation has opened up prospects for consumers to travel to more places at more affordable prices. The changes affect not just the low-cost carriers, but impinge on the business model of other carriers as well. Those dynamics are positive for European consumers and producers, and for the wider European economy.

In other areas, our record gives cause for caution. If we look at innovation in terms of the Lisbon Agenda, it is disturbing to note that as recently as 1990 US research and development expenditure on pharmaceuticals ran at only 70% of the European level. Today that position is reversed; that is a loss of European leadership. Twenty years ago, eight out of ten new drugs were patented in Europe. Today the reverse is the case. We need to stand back and ask why.

Larry Summers, former president of Harvard, said: 'For the first time in human history, we are going to face competition from low-wage, high human capital communities embedded in India, China and Asia.' He is right: not only in terms of the textile sector and the impact of low-cost labour on production and trade, but as China and India develop their intellectual property capacities and human capital we face a challenge here too.

In 2000 domestic Chinese firms or researchers made 50,000

patent applications. The pirate who has been pirating our IP is learning how to protect his own innovations. In 2004 the number of applications had doubled to 100,000, and this exponential growth is set to continue. Included in the total, Chinese universities now apply for 6,000 patents annually (second only to the US universities' 6,500 applications, and six times better than the best performance of European universities: 1,000 per annum in the UK). We cannot compete with such realities by ignoring them; we need to factor them into our debates.

We cannot choose utopianism as an alternative. We must also factor in the reality that our continent is old in more ways than one, notably in the demographic sense. In Wim Kok's phrase from the report on the Lisbon Agenda: 'The status quo is not an option.' In any number of areas transformation is delivering more for the transformers than for the non-transformers; reform is delivering growth inside the older EU, even within the more stagnant economies – the dynamic sectors, accepting realities and building their strategies on them, all pointing the way. The way forward is not to brush these realities under the carpet.

What Europe?

It would be very useful if our leaders remembered a phrase of Bertolt Brecht's: 'You cannot change the people.' Many have also paraphrased Cavour, father of Italian unification: 'Where are the Europeans?' With the passage of time, and generations that have lived through dreadful alternatives, we need to look at these emotive issues, not to abandon a good idea and its noble qualities, but to try to discover that missing link: a Europe without Europeans.

The European issue is also complicated by what we want Europe to be: some want a very strong, centralised federation; others see this as a nightmare. But with or without a constitutional treaty, it is frequently none of the above. It is very much an organisation that is radically less than what you might expect of a mature federation, and very much more than what you might expect of a mere intergovernmental organisation. The very in-betweenness is already a grey area. We invented this thing; nobody else had done it before.

Before we started turning the debate into one about constitutional treaties, we were very confused in our political discussions about what Europe is and where it should go. It is not a classical state, because the first thing a treaty defines is the border. It does not have government and an opposition. Nor does it have a standing army, or any of the classic public goods of a state: defence, police force, welfare system. Its budget – and we don't know what it is going to be – is radically smaller than that of a classical federation.

The states cannot absolve themselves of the responsibility for creating a partial sense of Europe over a long period of time. If 'Brussels' (in the generic sense) were a bank account, it would be filled with debit entries and no credit. For the things for which people take credit through the transposition of law are frequently the product of the natural genius of the domestic political class. But controversial things may be blamed on Brussels. Therefore there is an uneven quality in the communication of the totality of these things, and in that sense there is a communications issue. The procedure fails to communicate its commonness, even when it meets in common.

A final story: it is about Richard Daley, former mayor of

Chicago, famous (or infamous) from the riots at the Democratic selection convention in 1968. When he was re-elected, someone in his office wrote a speech. This happens in politics; and sometimes you read the words of the speech for the first time as you deliver them. Daley's speech said that the mayor committed his administration 'to ever higher plateaux of achievement'. As Daley read the speech for the first time, he declared that he committed his administration 'to ever higher platitudes'.

In that story is a conundrum for Europe: platitudes or performance. If we take a platitudinous road as a collective response to the current sense of angst, we would be travelling down the wrong road. The realities require us to focus and to try to be winners in the available context.

5

Healthcare as a driver of growth

Arne Björnberg

Healthcare services can be converted from being an increasingly difficult cost problem into becoming the largest service industry in society.

The reason we are experiencing a so-called healthcare crisis is because of healthcare itself. The capability of healthcare, aided by technology, has never been as good as it is today.

It is often said that rising costs are primarily due to the rising numbers of elderly people. But this is like saying that it rains a lot in England because people there carry umbrellas. It would be more correct to say that we have a lot of elderly people because of healthcare. Only twenty years ago, 75-year-olds who today get routine advanced surgery were left to die. For the past two decades, the life expectancy of an American has risen by more than six years; and four out of the six years are due to improved care for heart problems.

That is why doctors need to distinguish between the need for care and mere demand. Doctors have been doing this for decades; they are well trained for it and they do it every day.

It is nothing new, and constraints were much more restrictive twenty years ago than they are today.

The capability of healthcare is growing faster every year, whereas the European economy is not. As a result, given current financial methods, there will be a widening gap between healthcare capability and what is affordable.

At the same time, a tremendous opportunity exists: it will become possible to introduce attractive ways of consuming additional healthcare without doing what the public hates most, i.e. depriving them of services they used to enjoy. In other words we could keep healthcare at the present level, but also use the expanding capabilities to provide space for private healthcare consumption.

We are not in any way advocating that we imitate US social insurance ideology. What we do argue is that we should make it as streamlined and pleasant to consume healthcare services as it is to consume package holidays or Korean-made home electronics.

Who pays?

Now for a short lesson in national economics: what is the actual difference between a cost problem and an industry? The depressing fact is that whether an activity (a product or service) is a cost problem or an industry contributing to the GDP has absolutely nothing to do with the nature of the product/service. If enough people are willing to watch somebody smashing pianos with sledgehammers, piano-smashing will become part of the entertainment industry. So, then, what is the difference?



Figure 1 Healthcare for comfort?

A crude grouping of healthcare therapies. From left to right, columns represent therapies, where the degree of life-saving decreases and the degree of improving quality of life increases. The brick wall represents the present situation in Sweden, where therapies in the three columns to the left of ('inside') the wall are being paid for by public healthcare systems, whereas the right-hand column 'outside' the wall is not. Over the years, as medical science has been advancing, and as national wealth increases, the wall has been travelling towards the right in essentially every society.

The difference lies in the concept of the autonomous consumption decision-maker (ACDM), or more commonly the customer. But when somebody else is perceived to be paying, there is suddenly a difference between an ACDM and a customer. It is often argued that the demand for healthcare is unlimited since somebody else is perceived to be paying, and that this is unique to healthcare. It is important to stress that ACDMs cannot coexist with rationing.

The actual difference between a cost problem and a service is the number of ACDMs in a given market. In the UK, the National Health Service is the ACDM for healthcare services. In most other European countries, there are between 20 and 100: these are counties, insurance companies, *Krankenkassen* (sick funds/health insurers), etc.

Interestingly enough, nobody knows how many ACDMs are needed in a market before it can be considered an industry. If you have enough ACDMs, a human activity becomes an industry, regardless of the nature of the product or the service.

Some significant features of the situation are depicted in Figure 1. One is that the bulk of such healthcare, which in industrialised countries remains 'outside the wall', is not made up of diseases or ailments of a different kind to those 'inside the wall'. Most of the therapies in the right-hand column are dealing with *less severe cases of the same problems* that, if of greater severity, are being treated at public expense.

Another very important message of this figure is that distinguishing between patients' healthcare needs and 'mere' demands is not something that has been introduced in recent years as healthcare budgets have tightened; doctors have been trained for decades in classifying a patient's condition as 'a

problem that requires immediate action' or 'a problem that can wait', or which the patient will have to finance by means other than public funds. Unfortunately this assessment procedure is not very transparent. Making it easy to consume extra healthcare is beneficial not only for those who can afford it, but, as it eases the pressure on the public systems, for everybody.

How large can the healthcare market be allowed to become in the European Union? Interestingly, if there are enough ACDMs making consumption decisions, there are absolutely no limits to how large the industry can be allowed to become. A modern society requires 20% of the population to produce for our material needs, so in theory 40% of the population could be producing healthcare for the remaining 40%, so long as this is not financed by taxation, as this makes all other goods and services more expensive. If production is private, then consumption will be as high as people want it to be.

Why is the USA continually outpacing the EU in economic growth?

Employment in the service sectors has increased drastically, while employment in agriculture and manufacturing has actually fallen by more than 10% in actual numbers of people employed.

A major reason why the EU lags behind the USA is that we have blocked out what has been providing most of the growth in the United States by calling these services 'public services' and treating them as a cost problem, instead of stimulating their growth. A lower percentage of the population works in the manufacturing industry in the USA than in the EU, but

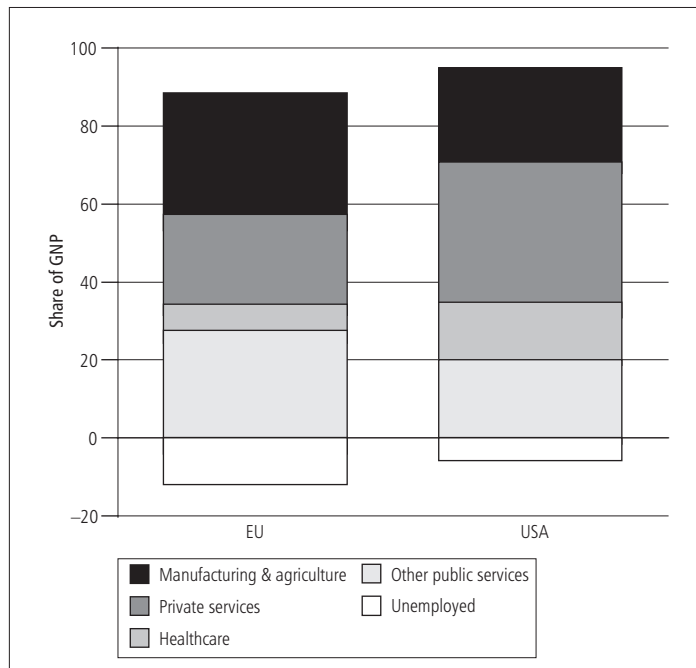


Figure 2 EU countries may have blocked the underlying growth potential of the healthcare industry by treating it as a cost problem rather than as a service industry

Percentage of GNP of various sectors in the EU and the USA. One striking property of the diagram is that it reveals approximately the same difference in the part of the labour force occupied in manufacturing and agriculture or in being unemployed (7% less in the USA) and in the part of the labour force working in the healthcare industry (7% more in the USA). The other striking difference is the distribution of private versus public services, with a heavy US emphasis on private services.

Source: Eurostat, 1997

many more work in services, not least in healthcare. As a consequence, unemployment in the USA is much lower.

There are good things to be learned from the Americans. One is that out of 300 million US citizens, 250 million get excellent-quality healthcare with no waiting lists. Europeans, looking at US healthcare, tend to focus on the ‘great American side effect’, the close to 50 million people (15% of the population) without adequate healthcare insurance. This is not a healthcare industry characteristic, it is social insurance ideology, and I am not suggesting we copy the American insurance structure.

In order to create growth, it is important to nurture those industries that provide a maximum of jobs per euro spent. Healthcare is perfect in this respect because, unlike major infrastructure projects such as building motorways, it is not capital intensive. Although there are significant export opportunities, healthcare (unlike software) cannot be outsourced to India or other emerging economies. The bulk of healthcare must be produced close to where customers live.

How large would the EU healthcare sector have been if we had treated it as a service industry and allowed it to grow? In my opinion, 10 million new jobs would be a very conservative estimate. The key issues are:

- 1 Creating smooth and streamlined financing solutions to make it easier to consume healthcare.
- 2 Prioritisation: unless assessment mechanisms become more transparent in order that patients understand why they have been refused public-funded treatment, it will be politically impossible to gain acceptance for these ideas.

Unlocking Ideas

Thus, the management challenge is: how do we go about transforming healthcare from being a cost problem to becoming the largest and most beneficent service industry on earth, without sacrificing equal access to quality care and avoiding the great American side effect?

I believe that, as desired by the Lisbon Agenda, the capacity for growth of up to €200 billion exists, within the world's largest service industry – healthcare.

part 2

Science and innovation

6

Biotechnology: a healthy revolution

Jan Remans

Healthcare trends – towards 2015

We stand at the threshold of an exciting new era in healthcare. The application of modern approaches and technologies brings the potential to radically transform public health and healthcare for those who cannot afford such care, while enabling unprecedented levels of care for those who can. Innovators and entrepreneurs who come up with newer and better ways of providing care are likely to benefit substantially – and they stand to make a real and very substantial difference to the lives of millions.

We are adopting increasingly integrated and more holistic perspectives on health and disease whereby we focus more on wellness and disease management, recognising that prevention and health promotion are not only more cost effective but are also more rational. In fact, it may already be too late when a patient develops symptoms of disease – hence an increasing focus on ensuring that early manifestations are identified, and

disease progression is halted and reversed before any long-term harm occurs. Care providers are under pressure to provide high-quality healthcare that is affordable to the consumer while still being profitable. All this has to be accomplished in a highly regulated healthcare environment.

There is growing interest and demand for wellness-oriented products, services and technologies. Arguably 'lifestyle' products and services, the market for nutraceuticals, cosmeceuticals and technology solutions for disease monitoring and management (including electronic medical monitoring devices), are growing at a rate at least twice that of pharmaceuticals.

The revolution of living things

Biotechnology will revolutionise life. Better disease control, custom drugs, gene therapy, age mitigation and reversal, memory drugs, prosthetics, bionic implants, animal transplants and many other advances may continue to increase human lifespan and improve quality of life. Some advances may even improve human performance beyond current levels (e.g. through artificial sensors). Research is also under way to create new, self-sustaining organisms.

Increased quantity and quality of human life are the most significant effects. Biomedical advances will continue to increase human lifespan in those countries where they are implemented. Such advances are likely to lengthen individual productivity, but will also accentuate such issues as shifts in population age, financial support for retired people and increased healthcare costs for individuals.

But we anticipate continuing controversy over issues such as:

- 1 *Eugenetics*: By 2015 we may have the capability to use genetic engineering techniques to 'improve' the human species. This will be among the most controversial technologies in the entire history of mankind.
- 2 *Cloning of humans*: Including concerns over morality, errors, induced medical problems, gene ownership and human breeding. Cloning, especially human cloning, has already generated significant controversies across the globe. Some believe, however, that human cloning may be accomplished soon if the research organisation accepts the high lethality rate for the embryo and the potential generation of developmental abnormalities.
- 3 *Gene patents*: And the potential for either excessive ownership rights of sequences or insufficient intellectual property protections to encourage investments.
- 4 *Privacy of genetic profiles*: The ability to profile an individual's DNA is already raising concerns about privacy and excessive monitoring. Examples include databases of DNA signatures for use in criminal investigations, and the potential use of genetically based health predispositions by insurance companies or employers to deny coverage or to discriminate. The latter may raise policy issues regarding acceptable and unacceptable profiling for insurance or employment. This is also worrisome because the exact code-to-function mechanisms that trigger many disease predispositions are not well understood.
- 5 *The safety and ethics of genetically modified organisms*: The danger of environmental havoc from genetically modified organisms (perhaps balanced by increased knowledge and

control of modification functions compared with more traditional manipulation mechanisms).

- 6 *The use of stem cells* (mainly human embryos) for tissue engineering.
- 7 *Concerns over animal rights*: Brought about by transplantation from animals as well as the risk of trans-species disease.

At the extreme, successful protest pressures on big biotechnology companies together with wide technology availability could ultimately drive genomic engineering underground to groups outside such pressures and outside regulatory controls that help ensure safe and ethical uses. Ironically, this could facilitate the very problems that the anti-biotechnology movement is hoping to prevent. Advances in genomics could promote a race between the threat of engineering and countermeasures. Thus, although genetic manipulation is likely to result in medical advances, it is unclear whether we will be in a safer position in the future.

Investment and genome decoding are fuelling the ability to modify and engineer organisms to provide needed capabilities, but social concerns are already affecting the generation and use of GM foods, with differences especially between the United States and the European Union. Optimistically, in 2015 GM foods will be widespread, resulting in significant benefits for food quality, global production and the environment. Policy controls or lack of investment might moderate the production and use of GM foods, leading to increased reliance on traditional mechanisms for food productivity increases and pest control.

Concerns regarding the following issues will grow over the next fifteen years:

- ▶ *Class disparities*. As technology brings benefits to some, it may leave others behind and create new class disparities. Although technology will help alleviate some severe hardships (e.g. food shortages and nutritional problems in the developing world), it will create real economic disparities. Those not willing or able to retrain and adapt to new business opportunities may fall farther behind. Moreover, given the market weakness of poor populations in developing countries, economic incentives will often be insufficient to drive the acquisition of new-technology artefacts or skills.
- ▶ *Reduced privacy*. Threats to individual privacy include the construction of Internet databases, increased sensor capability, DNA testing and genetic profiles indicating disease predispositions. There is some ambivalence about privacy because of the potential benefits from these technologies (e.g. personalised products and services). Since legislation has often lagged behind the pace of technology, privacy may be addressed in reactive rather than proactive fashion with interleaving gaps in protection.
- ▶ *Cultural threats*. Many people feel that their culture's continued vitality and even long-term existence may be threatened by new ways of living brought about by technology.

Technology's promise will have widespread effects across the globe. Yet these will not be uniform, playing out differently on

the global stage depending on acceptance, investment and a variety of other decisions. There will be no turning back, since some societies will avail themselves of the revolution, and globalisation will thus change the environment in which each society lives. This is certainly also true for healthcare.

Biomedical sciences

The biggest impact of the unravelling of the human genome will likely occur in the biomedical sciences. The sequencing of genomes represents only the first step in translating the newly understood genetic data to practical application. The implications are far reaching and will have a myriad of socio-economic effects, ranging from better and faster disease diagnosis to improved drugs, individually tailored medical treatments and more proactive disease prevention.

Diagnostics

Key drivers of growth in the diagnostics sector in the future are expected to include molecular diagnostics, point-of-care diagnostics and diabetes testing.

Recent developments in genomics and proteomics have fuelled rapid growth of the development and marketing of molecular diagnostic tools and technologies for research and future clinical application – for gene-based diagnostics, pharmacogenomic screening and diagnostics, and in high-throughput drug screening and discovery. Hence micro array-based diagnostic tools and DNA sequencers have witnessed growth in excess of 20% annually in recent years, while DNA synthesisers and nucleic acid amplification technologies have experienced growth exceeding 10%.

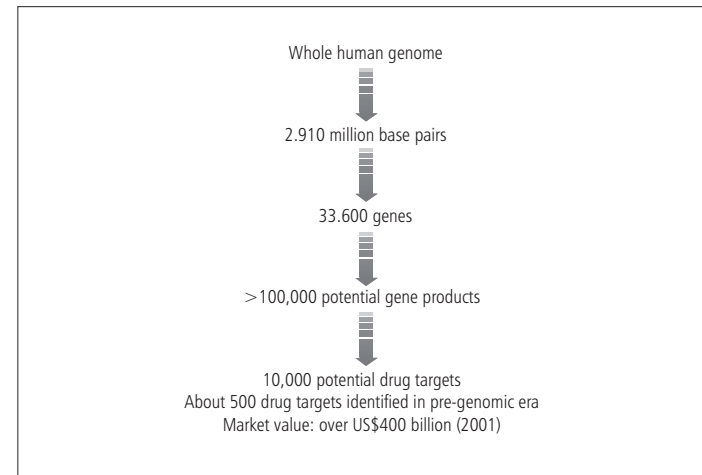


Figure 3 Implications of new findings in genomics and proteomics for drug discovery and development

Source: Lynk Biotech, 2001

Concerning point-of-care diagnostics, primary interest is expected to focus on rapid infectious disease diagnostics and drug testing, as well as cancer and chronic disease screening.

Pharmaceutical development

It is generally estimated that only 1 in 10,000 drug candidates makes it through the developmental process to enter the market. Even when a drug gets to clinical trials, only 1 in 5 will get to market.

Traditional drug discovery and development, including taking a drug candidate through pre-clinical testing and then the clinical trial and regulatory approval process, is a drawn-out

process, taking as long as ten to fifteen years or more, costing US\$800 million or more.

Individually tailored medical treatment

Advances in pharmacogenomics and increasing understanding of how genetic variations can contribute to varying drug efficacy and the risk of adverse reactions are pushing us towards personalised medicine. While a move in this direction will undoubtedly benefit individual patients, it may spell, in time, a move away from one-size-fits-all mass-manufactured blockbuster drugs towards having small batches of customised drugs made to order at friendly neighbourhood pharmacies or laboratories. Such dynamics will inevitably alter the face of the pharmaceutical industry internationally.

By 2015, one can envision effective localised, targeted and controlled drug delivery systems; long-lived implants and prosthetics; and artificial skin, bone and perhaps heart muscle or even nerve tissue.

Eventually, neural and sensory implants could radically change the way people sense, perceive and interact with natural and artificial environments. Ultimately, these new capabilities could create new jobs and activities. Such innovations may first develop for individuals with particularly challenging and critical functions (soldiers, for example, or pilots), but innovations may first develop in other quarters (such as the entertainment industries).

The opportunity to apply new tools and technologies to facilitate non-invasive, ambulatory measurement and monitoring of biometric parameters for wellness and disease management is enormous. This is especially true in relation to chronic condi-

tions such as diabetes mellitus (affecting 10% or more of most adult populations), hypertension (affecting about 25% or more) and lipid/cholesterol abnormalities (affecting 17% or more).

A recent study in Germany showed that annual medical costs for a diabetic with no complications were about €2,000 a year, but exceeded €5,000 when complications developed. The reality is that complications arising from diabetes and hypertension are essentially preventable, and patients can be maintained in good health with more effective control of disease. Such solution may bring savings of 50% or more in direct and indirect healthcare costs, while maximising patient well-being and improving patient-provider interaction.

Chips

The deepening relationship between the electronics and life science sectors is responsible for creating a growing range of novel technologies such as gene and protein chips. It also creates varied potential uses, including rapid disease diagnosis and management, and 'high-throughput' natural product screening, as well as cutting-edge medical devices for patient monitoring and management.

Telemedicine

This refers to the electronic transfer of patient-specific medical information from one location to another for the purpose of improving patient care. This broad definition encompasses any technology used for the delivery of healthcare services and medical education over a distance, including remote monitoring of patient vital signs for disease management, teleconsultation and telesurgery.

Medical monitoring is an option that should be further developed. The entire range of new technological services lowers healthcare cost for both individuals and society. They lower the individual expenses of users, who are able to stay home for longer instead of going into a nursing home. They also lower health insurance costs, since fewer fixed care costs must be paid. In addition chronic illnesses may be better monitored at a lower cost, while complications and hence also admission to hospital may be prevented more efficiently.

The following strategic changes are essential in the pharmaceutical market:

- Government should create an environment that stimulates the pharmaceutical industry instead of stifling it. This applies to fiscal, economic and social regulations.
- For patients, the government should guarantee rapid access to innovation. It has to be proved how and how much can be saved through innovation as opposed to using existing products.
- The government should take responsibility for open communication, for example a website with official information.
- Advertising of registered medicines should remain strictly subject to regulation. The source of information must always be clearly mentioned.

Patient-driven medicine

In setting priorities in healthcare the government should see to

it that scientific criteria are followed that focus on the parties most involved, namely patients.

This has alarming consequences for the affordability of healthcare. On the one hand patients and their families want the most advanced treatment methods, affordable or not. On the other hand we want the latest technological options to be available to everyone – the best for everyone. This tension puts such a strain on joint-liability health insurance that we have to improve this system in order to save it.

Free choice is an essential feature of our healthcare. It explains to a large extent the attractiveness of our care system. Patients are able to choose their own insurer, and also between a high-risk lifestyle and an average-risk lifestyle. Reimbursement of specific services can be modulated depending on the patient's lifestyle. For it is reasonable to consider that the reimbursement of medication for lung and blood vessel disorders should also be determined by whether the patient smokes or not.

With the rational and more functional use of medical services, personal prevention of adverse factors could become a *sine qua non* condition for bearing medical expenses in mandatory insurance based on joint liability. Patients, however, maintain free choice. They could (or would have to) enrol in additional insurance, of their choice, but where they bear the consequences of variable premiums. A financial bonus would be an incentive for people to take responsibility themselves for a healthy lifestyle.

If we are to manage healthcare from this patient point of view, it is crucial that patients get their own unregulated representation in the consultation model with the government, insurance companies, care institutions and caregivers. Patient

groups should be able to structure themselves with experts in their disorders and with subsidies from the government. In this way patients would take on increased responsibility for an optimal healthcare system for everyone. In the transition from passive risk insurance to active risk management patients would increasingly take over the reins: through their own free choice, health insurance would remain affordable.

Two main themes can then be developed, namely the transition from essential care to customised care and from mandatory health insurance to customised insurance. The boundaries of this individual model should be established in a continuous social and political debate.

Earlier attempts to set priorities derailed in terms of two aspects. On the one hand they had insufficient insight into the difficulties of reconciling efficiency and equality. On the other hand the problem did not appear solvable based on sheer justice considerations, since many sources of inequality run through the debate. That is also why we had better focus the dynamics of health standards on the wishes and needs of the sick. This is in fact a matter of health democracy.

7

Biotechnology and the promise of tailor-made medicine

Anders Sandberg

New technologies are emerging in medicine and their interactions may affect healthcare policy.

Usually, healthcare policy discussions end up at the questions of who pays, and how much freedom will patients get? We tend to forget that modern medical practice is shaped by technology. Medical technologies have changed the way in which we practise medicine, and they are going to change these even further.

The Eudoxa think tank performed a study in 2005 on how Swedish healthcare may be perfected by using some of the emerging technologies, and in certain areas indeed radical changes are possible. This will require political and regulatory changes.

Pharmacogenomics, or smart drugs, are appearing; this doesn't mean that they make you smarter, but that they act smartly in your body. Once upon a time, inventing new drugs was a matter of trial and error: you tried things out on people and sometimes they got better. Once medicine got a little more scientific, products were tried on many people, and if most of them got better, fine.

Today we have a lot more information about how the body actually works, which enables us to undertake rational drug design. But the interaction between the drug and our genes has an important effect. This produces some interesting challenges for the pharmaceutical industry. During the Korean War, anti-malaria drugs were given to soldiers and the side effect was anaemia. Most of the soldiers were black, and it was discovered that this population lacked the enzyme to break down the drug. This stimulated serious research into how drugs affect different people.

When I take a medicine, I obviously pray that it does indeed have the expected effect. But my body may break it down very quickly, in which case I don't get much out of it; I may break it down very slowly, which means that its effect will be excessive, possibly entailing side effects and poisoning. It may turn out that the drug is not absorbed in the appropriate way, or that it affects me in some other way.

In the early days, epidemiological studies could determine that a certain population might be genetically predisposed towards some particular side effect. But in the 1990s, a wonderful synergy occurred as we simultaneously achieved faster computers and better genetics. We suddenly had enormous databases which could be searched very rapidly. This produced genomics: the combination of genetics and informatics. You could combine the analysis of drug reactions with people's genetic fingerprints. Thus we could get the right dosage of the right drug to the right person.

Can we use this mass of information to help people and keep the pharmaceutical industry profitable without cumbersome regulations?

Inside each cell are the chromosomes, which are really piles of DNA. The DNA molecule encodes the proteins manufactured by the body; a regulatory structure tells the cell what substance to produce at what time in response to the environment. A gene is essentially a recipe for making a protein. The proteins act inside the cell, and their interactions can be very different. Usually, we have different versions of a gene, inherited from both father and mother. In most cases they are roughly equivalent, but sometimes variations are quite significant. A typical example is the gene for Cytochromoxidase C, a very important enzyme which breaks down many molecules in the body, including many pharmaceuticals. Certain versions are much more efficient at breaking them down, which means that the people with this version will automatically need a higher dosage of a given drug. Conversely, the people with the 'slow' enzyme will end up with the side effects. All this occurs because of random differences in the DNA.

Before genomics, the doctor would try different dosages over time, but in the case of depression, for instance, the patient would suffer while the doctor was determining the right amount.

Drug development also faces the problem that some people do not react at all to a certain medicine, even though large proportions of the population respond well. Breast cancer genes are very vulnerable to certain chemical interventions. But only the individuals with the particular mutation causing the cancer will benefit from the drug. Similarly, HIV patients with rare variants have to be isolated in order to develop a drug that will benefit the majority.

This obviously has a great impact on drug development.

Sadly, although science and technology are advancing, the number of drugs is not increasing. The reason is that we are demanding a lot from the drugs. Discovering new drugs is an excellent area for genomics: it is fairly easy to come up with new candidate drugs. The problem is convincing your boss that a certain drug is worth pursuing, all the way from animal testing to human trials. At each step, the cost increases enormously. Initially, computer simulations are possible. But there are always unexpected side effects. Viagra, for instance, was initially intended as a blood pressure drug.

Pharmacogenomics can hopefully make these early trials cheaper by selecting more genetically homogeneous populations displaying similar reactions, in order to gain a clear understanding of the side effects. Later on, in clinical trials, we might also select more promising sub-populations, so that the drug might be approved at least for these categories. But this will create a situation in which a drug exists for a minority but the population at large will not benefit.

In addition, we live in a very risk-averse society. In the later stages of development, other groups become involved who believe that the most important thing is that the future drug should not be too expensive. In Sweden, patients become more cheerful as new drugs and technologies are developed, whereas politicians fret about paying for them.

Pharmacogenomics makes it easier to test for adverse reactions. A DNA chip's surface is covered with different DNA sequences. When dipped into a sample, some of the DNA in the sample sticks to it. Using various optical measures, you obtain a fluorescent trace showing a fingerprint of the genes of the individual. This provides for cheap genetic testing, and in the

future it might be used against bacteria and viruses. If I see my doctor with the flu, he can check which version I have and give me the right medicine. Also, I may discover that I am particularly susceptible to a certain disease, which may hit me in my eighties.

This will of course create interesting dilemmas for the insurance companies, which are generally not allowed to screen for this kind of information. In Sweden, regulations determine that only a particular medical agency may decide if I should get genetic testing; but I can also get it on the Internet! Before, breast cancer was considered one single disease. Today we know that it is caused by several different potential mutations. Some are easy to define and to treat, others are ill defined, and others yet are purely environmental. Suddenly breast cancer has dissolved into a number of different diseases. We may find great drugs for some of them, but possibly only for a fairly small patient group. We might end up with orphan drugs that are not economically viable.

But the common diseases actually have different origins. There is a strong suspicion in the neuroscience community that schizophrenia is not a single disease, but might in fact have ten different core causes.

As a computer scientist, I always tend to bring up Moore's law to illustrate how computing power multiplies over time. Moore's law for genomics shows the length of DNA which can be sequenced at a certain time and a certain cost; this increases extremely rapidly. Regulations might say otherwise, but we are going to see basement gene hackers very soon. Thanks to nanotechnology we will see laboratories on a chip, equipped with different sensors to analyse liquids. In the future, hospital

labs might be replaced by laptops in the doctor's office, or perhaps in the patient's home.

Although this laboratory chip is technically feasible, it will be rather tricky to fit it into our current healthcare organisations. The hospital labs will fight very hard to show that they are necessary, and this might even be true.

The future has an annoying tendency to arrive in the wrong order and at the wrong speed. We are getting wonderful diagnostics tools at present, which enable us to diagnose diseases that we cannot do anything about! This is rather depressing, until you realise that many of these diseases will not strike you before old age, and that quite a few things will happen in the next 20–30 years. People suffering from cystic fibrosis have experienced increasing life expectancy. Treatments have improved faster than the rate at which people are ageing. We may be surprised by the diseases that don't become more prevalent, but we cannot know which they will be, so it is hard to make predictions.

We are collecting incredible amounts of information in genomics nowadays. This is also the case in neuroscience. We have so much data we do not always know what to do with it. Of great importance are the chemical reactions in the different parts of the brain, and the consequences of them. As we start to manipulate the different areas, we may actually be able to intervene in some complex cognitive functions.

Emotional neuroscience ten years ago was truly embarrassing: if you were not doing research on depression, you were not doing serious research on emotions. These days things are much more interesting. If you do brain scans on people in love, a mother seeing her child or somebody listening to beautiful

music, you can identify the commonalities of pleasure and enjoyment. Some of these emotions have fairly simple chemical systems. It turns out, for instance, that some people are born with a lower set point for happiness than others! This keeps all the ethicists at Oxford very busy, wondering whether these people should be treated. Come to think of it, maybe we should treat everybody to make them happier!

The interesting thing is that we can go all the way today, from a single molecule or receptor, and build a case for how this affects memory and personality. We are still far from doing this efficiently – for instance, in the case of memory disorders – but we are getting there. It will take a long time, however, to discover how we may shape the brain through drug development. And of course, ethicists and social commentators agree that it is better for people to suffer a bit ...

Consider a memory-enhanced mouse, genetically modified to make it learn better. It is also more sensitive to pain, because the modified receptor is also used for pain reception. This could probably also work in humans, although both technically and ethically we are still far from trying it out. There are already drugs that affect the memory, and doping in sports has existed for a long time. But in a few years' time, the athletes competing are not going to be as strong and fast as the elderly people watching them on television. If gene therapy is prohibited in professional sports, it is still possible for a patient who has broken a bone (although he won't be allowed to participate in the Olympics afterwards!). Concert musicians often use beta blockers before a performance. Does this mean that classical music is suffering from a doping epidemic? Does it affect the music?

A friend of mine makes the distinction between ‘drugs’ (narcotics, etc.) and healthy food, such as bread. I recently ate bread containing ginseng and other ingredients that are supposed to make me brighter and smarter. Compare this to the difference between heroin and ritalin; the latter is chemically very similar to amphetamine. But if I take ritalin to get high, it’s a narcotic. If I take it because I have attention problems, it is a medicine. If I take it just to enhance my attention (which in some cases it does) we enter a grey area. Instead of refusing to ‘treat healthy people’, we may, with more precise diagnostic tools, discover that nobody is perfectly healthy; we could all be better off.

Technology poses a number of challenges, although some of them look more daunting in a slide presentation than in a lab or a clinical trial. Many of them will become more relevant for healthcare policy. The problem in current society is that risk aversion begets risk aversion, leading to policy-making that fails to recognise these opportunities.

8

Intellectual property versus antitrust rules

Duncan Curley

Has the European Commission’s interpretation of intellectual property rights (IPRs) and their interaction with competition rules evolved, and if so how and why? Does the Commission’s interpretation and implementation of competition rules take place across the board? In other words, is it treating different areas of technology comparably; are principles applied to pharmaceuticals in the same way as to software? The issue of incremental (or ‘follow-on’) innovation is not treated uniformly: in terms of software, follow-on innovation is mostly celebrated for creating competition, whereas new pharmaceutical products are usually described as ‘me too’ drugs. What is the proper approach? And should there be an EU policy to address this?

Slow progress

The goal to make the EU the world’s leading knowledge economy by 2010 was set in 2000 in Lisbon; as we are now

in 2006, let us say that progress has been a little slow.

There can be no debate that there is a need for strong IP protection in Europe. Patents protect inventions with industrial applicability, whereas copyright protects creative expression. They are exclusionary monopoly or quasi-monopoly rights.

People generally think of competition law in the sense of attacking monopolies, i.e. competition is there to reduce prices and to facilitate consumer choice. Some therefore perceive a clash between competition laws (intended to open up markets) and IPRs, which may lead to higher prices. Recent statements from the European Commission, however, have stressed the complementarity of the two, particularly in fostering innovation.

Legal instruments

A key component of policy-making these days is of course the Lisbon Agenda. Ms Neelie Kroes, Commissioner for Competition Policy, said in a speech in Paris (June 2006) that she is committed to ensuring that competition policy plays its part in fulfilling the Lisbon Agenda.

How does the rhetoric measure up to the reality of the case law? Let us look at the two main limbs, Articles 81 and 82. Articles 81 and 82 of the EC Treaty are the legal instruments used by the European Commission to facilitate the market economy in Europe. The first prohibits cartels, but it can also impact on many kinds of contractual agreements, such as exclusive distribution, R&D agreements and IP licensing and technology transfer agreements. In 2004, the Commission radically updated its competition policy in terms of IP

licence agreements. It brought in a new technology transfer block exemption, intended to give much greater freedom to companies licensing their IP. The new rules on the application of Article 81 were firmly in accord with the Lisbon objectives, at least according to the Commission.

Article 82 is aimed at a quite different kind of mischief. It is used to regulate unilateral conduct of larger market players. Cases under Article 82 are rare, and those involving intellectual property rights even more rare. It is aimed at dominant firms, with a strong market position or near-monopoly, that can act independently from the other market players. A shortage of competition can lessen the incentive for a dominant firm to increase its performance, in terms of cost reduction and innovation. Article 82(b) is the provision that specifies that, in certain circumstances, dominant firms may not restrict access to their technology. This raises the question: to what extent must dominant firms open their doors and license their IP if asked by their competitors? The European Commission will intervene in some circumstances, and the key issue for companies is, of course, what are these circumstances?

Case law

The Magill precedent

The Magill case involved a comprehensive television guide in Ireland that intended to list all TV programmes for all channels. But the TV broadcasters all had their own listings and asserted their copyrights in order to sue Mr Magill for infringement, thus preventing his TV guide from being published. The European Court of Justice then held that 'exceptional circumstances'

warranted a compulsory licensing of the copyrights belonging to the broadcasters. The key point was that Mr Magill was offering a brand-new product not yet on the market, for which there was proven customer demand, but this was being frustrated by the copyrights held by the broadcasters.

In the mid-1990s, access to IP under Article 82 was limited to exceptional circumstances. Since then, access to technology has become more important and IPRs have become part of the mainstream business environment. The European Commission has arguably become more interventionist when it believes that IPRs are not being exercised in a way that is commensurate with fair competition.

The IMS Health case

IMS Health is a large provider of pharmaceutical data. It owns a copyrighted database containing sales data for the German market. A company called NDC wanted to get into the market for selling such data with a very similar database. IMS sued NDC for copyright infringement; NDC then turned to the European Commission. The Commission granted a decision forcing IMS to grant a copyright licence to allow NDC to get into the market. The President of the Court of First Instance subsequently annulled this decision and later the case went to the European Court of Justice. What is important to note is that NDC was proposing to launch a product similar to IMS Health's own product, so the case is not comparable to the Magill case, which involved a brand-new product.

The Microsoft decision

We will focus on the work group server or interoperability

aspect of the Microsoft decision, since this is the most relevant to the IP/antitrust debate. Microsoft's Windows operating system consists of software that controls the functioning of computer hardware. A server, on the other hand, is essentially a powerful computer whose main role is to organise and manage network communications between different PCs. Work group servers are smaller and handle certain services (e.g. file and print) for computers that are linked together. Microsoft has a very strong market position for PC operating systems: Windows has a market share of more than 90% and has been described as 'ubiquitous'.

The case was launched because Sun Microsystems wanted to offer its own work group server operating system which would be compatible with the Windows PC operating system. In order to do so, Sun needed information on the MS work group system to ensure interoperability. Microsoft refused to supply this technical information. In its March 2004 decision, the Commission ordered Microsoft to provide the information to let Sun develop products that could interact with the Windows operating system on a 'reasonable and non discriminatory basis'. By doing so, the Commission tried to open up the market for work group server operating systems by allowing competitors such as Sun into the market.

What about the IP rights? Microsoft claimed that, to comply with the decision, it would have to grant an IP licence in order for companies like Sun to use the information lawfully. In fairness, the Commission did not shy away from the far-reaching nature of its order. In paragraph 546 of the decision, it stated that 'It cannot be excluded that ordering Microsoft to disclose [its] specifications and allow [...] use of them by third

parties restricts the exercise of Microsoft's intellectual property rights'.

Microsoft claimed, in my view correctly, that the Commission's disclosure order was unprecedented and that this would have adverse effects on its own incentives to innovate and develop new products. The Commission – and this is the most interesting aspect of the decision – then turned Microsoft's argument back on the company and said that it was stifling innovation in the work group server market, since all the players would gravitate towards the Microsoft standard. The Commission stated that 'The major objective justification put forward by Microsoft relates to Microsoft's intellectual property over Windows. However, a detailed examination of the disclosure at stake leads to the conclusion that, on balance, the possible negative impact of an order to supply on Microsoft's incentives to innovate is outweighed by its positive impact on the level of innovation in the whole industry ...' (paragraph 783).

This is confirmed further on in the decision: 'The need to protect Microsoft's incentives to innovate cannot constitute an objective justification that would offset the exceptional [Magill-type] circumstances identified', in particular Microsoft's very large market share.

The Commission's argument proceeds on the basis that, if Microsoft were allowed to continue its behaviour, innovation would be stifled in the work group server operating systems market. But the decision does not properly address the wider implications, which include the erosion of IP protection for dominant firms. This is a serious issue. According to Chris Parker, Director of Law and Corporate Affairs at Microsoft, 'A crucial part of this case rests on the rights of companies to

invest in research and development, innovate, produce new products to meet customer demand and then retain the right to earn a return on that investment.' In other words, IP law would ordinarily give Microsoft the right to retain any profit on licensing or indeed to choose not to license at all. The Commission's order takes away that option.

Did the Commission get its balancing act right? According to a report prepared by the Economic Advisory Group for Competition Policy, as part of the European Commission's recent review of policy under Article 82 (July 2005):

... even if a refusal to deal harms consumers in the short-run, it may be socially beneficial in the long-run. If the bottleneck is the result of investment or innovation activities of the dominant firm then forcing the firm to give its competitors access to the bottleneck is an expropriation of the returns of the firm's efforts. This may discourage this and other firms from investing in the future, and it may reduce incentives to innovate. Tolerating a (temporary) monopoly may be the best way to promote investment and innovation incentives ...

According to Microsoft, the European Commission 'has ... [committed] ... the biggest encroachment on intellectual property in European competition law history'. It has '... opened the vaults of a bank' to hand money out to passers-by (Microsoft's counsel, Ian Forrester, QC, before the Court of First Instance, April 2006).

An Article 82 policy review is under way. The Microsoft decision is on appeal to the Court of First Instance. It is a question of 'watch this space'.

9

Intellectual property and competition

Manuel Campolini

There are four principal characteristics of the pharmaceutical industry. First, the scale of R&D investment is unrivalled. Approximately \$800 million is needed to develop a new product (this includes failures), which makes the industry very dependent on a small number of 'blockbuster' products (sales of more than \$1 billion). Second, the pharmaceutical industry, unlike other businesses, is subject to stringent government-enforced price controls (at least in Europe) while at the same time public authorities are the main purchaser. Third, it depends heavily on the effectiveness of the intellectual property (IP) system: patents are often registered in a multitude of individual countries and the EU. Last but not least, the consumer – patient – wants the best product – and immediately – particularly when confronted by lethal diseases such as cancer, Aids or hepatitis. In Belgium a new breast cancer drug was not yet on the market because the reimbursement procedures had not been completed. The product was considered to be highly effective and the public pressure was so high that the

authorities had to put it on the market before the granting of the final price for reimbursement. Pharmaceutical products are therefore not like other products.

There are other important key features; one is strong product competition through innovation. This is in the first instance related to the research and development of new products. It is also related, however, to incremental innovation: within the same category a 'me too' product making 'only' an incremental improvement may have a greater therapeutic value than an entirely new drug. A further feature is parallel trade, which is mainly caused by disharmonised price/reimbursement systems: Product x may be bought at a low price in Greece and imported to the UK, where the price is much higher. The different prices are directly or indirectly imposed on the company by the national public authorities. The last is generic competition.

Competition rules should be understood and applied taking into account the above. Some recent and pre-eminent examples include:

1 The Bayer case

In 1991 Bayer was accused of restricting the supply of its anti-hypertension drug Adalat in France and Spain. As prices for Adalat were lower in these countries, a considerable parallel trade from France and Spain to the UK had been generated. Bayer reacted by implementing a supply policy corresponding solely to the French and Spanish market needs. The European Commission considered that there was a tacit agreement between Bayer and its wholesalers and imposed a fine on Bayer for infringement of EU competition rules (Article 81, EC).

In October 2000, the European Court of Justice delivered its judgement regarding supply restrictions implemented by Bayer in order to prevent parallel imports. The Court of First Instance considered that these restrictions did not contravene European competition rules as long as they were not adopted pursuant to a concurrence of wills between the manufacturer and domestic suppliers and did not amount to an abuse of dominant position. This Commission decision was therefore overruled, as no evidence of the existence of an agreement was provided by the Commission.

Bayer's position was crystal clear: its policy aimed at preventing parallel trade. The court observed that '[n]or, finally, can the Commission rely in support of its argument upon its conviction, which is, moreover, devoid of all foundation, that parallel imports will in the long term bring about the harmonisation of the price of medicinal products'. The Commission appealed this judgement but the European Court of Justice confirmed the decision of the Court of First Instance.

2 Syfait versus GSK

The second case relates to Article 82, EC (abuse of dominant position). GlaxoSmithKline (GSK) refused to meet the Greek wholesalers' demand in full in order to avoid parallel trade from Greece of its patented products. Advocate General Jacobs said that a refusal to supply might be acceptable because of the characteristics of the pharmaceutical industry, i.e. government price controls on the products, the consequences for innovation and the absence of benefit for consumers. Unfortunately the European Court of Justice declined its competence.

3 GSK versus Commission (Spain)

GSK was prohibited by the Commission from selling products to its Spanish wholesalers at different prices (a dual pricing system), i.e. lower prices when the products were sold in Spain and higher prices when the products were sold in other EU member states (mainly the UK). In this case, an agreement between GSK and its Spanish wholesalers existed in the form of agreed General Sales Conditions that incorporated this dual price system.

The court has considered that GSK's request for an exemption (Article 81.3, EC) was not examined by the Commission with sufficient thoroughness. Therefore, the Commission's decision is annulled in that it rejects GSK's request for an exemption. The CFI reasoning suggests that the Commission did not take into account the specificities of the pharmaceutical sector and did not balance the restrictive effects of such an agreement with its potential to increase, or at least to maintain, the availability of R&D investments, which are ultimately beneficial to consumers. As such, however, this case is not IP-related, but with its focus on innovation it is of interest from a patent standpoint.

4 AstraZeneca

In 2005, AstraZeneca was fined for abuse of dominant position in a case directly linked to IPRs and competition. The first of these transgressions was 'giving misleading information to several national patent offices, resulting in gaining extended patent protection for Losec through so-called SPCs [supplementary

protection certificates]’, while the second was ‘the misuse of rules and procedures applied by national medicines agencies, by selectively deregistering the market authorisations for Losec capsules in Denmark, Norway and Sweden with the intent of blocking or delaying entry of generics firms and parallel traders’.

On the matter of competition, Commissioner Neelie Kroes declared:

I fully support the need for innovative products to enjoy strong IP protection so that companies can recoup their R&D expenditure and be rewarded for their innovative efforts. However, it is not for a dominant company but for the legislator to decide which period of protection is adequate. Misleading regulators to gain longer protection acts as a disincentive to innovate and is a serious infringement of EU competition rules. Health care systems throughout Europe rely on generic drugs to keep costs down. Patients benefit from lower prices. By preventing generic competition AZ kept Losec prices artificially high. Moreover, competition from generic products after a patent has expired itself encourages innovation in pharmaceuticals.

Losec was launched in 1987, and had a superior therapeutic efficacy compared to older products. It became one of the most successful products in the 1990s and made \$6.3 billion dollars in 2000. This is the type of blockbuster product needed to fund research and development, and to finance products that are not necessarily less useful but are less profitable.

The Supplementary Protection Certificate (SPC) extends

patent protection for a maximum of five years after expiry. In order to obtain an SPC, AstraZeneca submitted an incorrect date. Litigation started in the late 1990s and judgement was handed down in 2003.

According to the Commission, Losec holds a dominant market position and the other products did not exercise a significant competitive constraint; whereas AstraZeneca argues that it is one of several treatments available.

Considering internal documentation, the sequence of actions and behaviour towards patent offices and courts, the Commission concluded that AstraZeneca’s conduct was abusive. AstraZeneca responded by pleading good faith; that alternative solutions existed for the registration of generic products; that a company is free to withdraw its products from the market; and that the tablet format of Losec presented benefits for patients.

The deregistration issue relates to the switch from Losec capsules to Losec tablets in the late 1990s. Both products were therapeutic equivalents. The capsule form was withdrawn from several high-price markets, e.g. Sweden and Denmark. As a consequence, the Swedish authorities decided that the import licence for Losec capsules needed by parallel traders was no longer valid, since Losec no longer existed in capsule form on the market. It took five years to get a judgement from the European Court of Justice overruling the decision of the Swedish authority.

The deregistration also had consequences for generic entry. After the data exclusivity expired, a generic company registered an abridged application for the Losec capsules. Approval was granted by Danish authorities, but was challenged by Astra-

Zeneca, again referring to the fact that Losec capsules were no longer on the market.

Conclusion

Is there conflict or coexistence between IP and competition? It is not easy to provide an answer in this specific case. Losec is the most emblematic case as it directly relates to IPRs. AstraZeneca has underlined that this would be the first case ever where an abuse is constructed based on the way in which a company acquired an IP right. In this case, however, was it really the issue of IPRs at stake? This is not certain, but the point needs to be clarified.

This being said, the application of competition rules to IPR-related issues introduces an additional factor of greater uncertainty. As far as abusive conduct is concerned, the question is: can the solution be found in the IP law system? The IP system is already largely self-regulatory. It might also be improved.

part 3

Patient empowerment

10

The health consumer vision

Johan Hjertqvist

The Health Consumer Powerhouse (founded in 2004) is a 'do-tank' rather than a think tank. This means that it is not confined to presenting brilliant ideas on health-care; it also aims at developing tools for consumer empowerment. For example, it presented the Health Consumer Index in Sweden in 2004, and in 2005 it launched the European Health Consumer Index. These measure the degree of consumer friendliness of various European Union health systems. Today it would be appropriate to label the Powerhouse an independent provider of healthcare analysis and consumer information.

Our core message is focused on health consumers and their needs.

To quote a German researcher, Professor Ilona Kickbusch, 'health is the core of modernity'. Indeed, it has increasingly become the cornerstone of modern society. We also know from research carried out by the Stockholm Network¹ that patient mobility, the active search for good healthcare and treatment beyond national boundaries, is a key indicator of a modern

trend. Roughly two out of three Europeans are ready to look for treatment abroad if the public or private insurance financing is portable and may follow the patient. This is remarkable, since a generation ago nobody would have thought about this option.

Three out of four young Europeans are disposed to this kind of mobility, as are a majority of senior citizens. In Sweden, in spite of socialised healthcare, people welcome this opportunity, which is also supported by the European Court of Justice. Indeed, 98% of Swedish people think that waiting times are a good indicator of healthcare quality. As may be expected of a politically planned healthcare system, however, only 15% of patients are satisfied with current waiting times, with 85% saying that being treated at a suitable time and place is important to them. People are thus becoming quite demanding regarding access, quality, choice and information from their healthcare providers – 77% say that giving patients more information about their illness would improve the standard of health services. There is strong belief in the individual patient's ability to take action, based on sound information provision.

Two out of three EU respondents say that without further reform the standard of health services will decline. This is a very significant conclusion for public policy-makers.

Clearly, something important is going on. In systemic terms, the person whom we still call the patient – meaning somebody who humbly waits in a long queue for the doctor to pronounce a judgement – is changing radically. From having been on the lowest level in a big hierarchical system, the patient is becoming one of many players in a market situation, able to take initiatives, with the goal of becoming more of an equal to physicians. He/she is not a simple receiver of services, but a partner in terms

of funding. He wants to take part in solving the problem, and not just wait for somebody to solve it for him; he is proactive rather than reactive, looking for information about treatment, even without being ill. He believes in his own responsibility – and indeed his own capacity – for inputting knowledge into the process. This means being demanding, comparing and evaluating services, asking for information and using his own judgement.

Shocking facts

The 2006 Euro Health Consumer Index, which is the first tool to analyse to what extent national healthcare systems meet consumer demand, reveals some remarkable, even shocking, facts:

- ▶ Half of Europe's healthcare systems deny patients access to their medical records or to a second opinion.
- ▶ Only one European country (the UK) provides patients with a service provider catalogue with a quality ranking.
- ▶ Waiting periods are common. In three-quarters of Europe's countries, you are likely to have to wait more than three weeks to have your cancer treated.
- ▶ In just a handful of countries can one find a consumer-friendly pharmacopoeia, assisting you if you want to learn about your options, as well as the side effects from medication.
- ▶ In two out of three countries, the government delays the introduction of new medicines into the reimbursement system.

A central shift

This is a central shift in values – a historic clash, moving from a paternalistic or Taylorist model (the foundation of the welfare state) towards modern society and individualist values. We move from social engineering, where public goods are allocated by medical experts and bureaucrats, towards a system where the informed consumer may compare market services in partnership with physicians, making choices. Doctors are no longer unquestioned authorities. Healthcare systems can no longer deliver given answers.

Traditionally, healthcare has been a political battleground, especially in countries like Sweden where ideology still prevails. In November 2004, I testified as an expert witness in a hearing before the European Parliament on the services directive. One of the thorny issues concerned was whether to include healthcare or to consider that health is a public good that cannot be subject to competition. Unsurprisingly, I argued that healthcare services should be portable and that it would be beneficial if, for instance, German providers could set up shop in Sweden. In Sweden this is a very sensitive matter, unlike in many European countries, where the issue has not been similarly politicised. A movement towards something we may label ‘service democracy’ should change this, as healthcare becomes more consumer driven, breaking up the monopolies and bringing in pluralism, in provision of services and also in funding.

Accountability and governance

Last but not least, the lack of incentives in many of the EU

healthcare systems should be replaced by mechanisms of accountability and governance, provided we allow the health consumer to become a player who is not compelled to accept waiting lists and poor quality.

To some extent, the existing systems have already affirmed this important value shift through their actions. The movement for patient rights is developing quickly, for example in the UK. Every EU citizen now has the right to move across borders, taking public funding with her, if her home country cannot guarantee treatment within a reasonable time (although it remains for the definition of the latter to be more tightly defined by court rulings). Clearly, two years is too long for a hip replacement, but whether the limit should be three or eight months, for instance, has not been determined. The European Court of Justice Watts case in 2006 indicates that the Court finds waiting times for planned surgery of more than three months unacceptable. In addition, a patient may look for treatment abroad if her own country doesn’t provide the service in question. Many governments have been shocked by this: in Sweden, politicians were appalled to discover that the rulings of the European Court also applied to their country.

In terms of access, all governments are working hard on reducing waiting times. They have promised to improve access (at least when elections are coming up). Still, access in Europe overall has improved considerably in the last five years, and eventually mobility will become a reality, not only for patients but also for providers. It has yet to happen in funding, which is the most critical and sensitive element: it is much more painful for politicians to open up funding to competition than to increase the number of providers. All this is of

course contingent on the EU living up to the goals of the Lisbon Agenda by improving economic growth, through making the European economy more competitive and knowledge-driven.

The EU and healthcare

Medical progress is of course paramount, but it is not directly related to political decision-making in parliaments around Europe. Although some structures of economic planning remain, politicians generally refrain from making five-year plans, stipulating new cures for cancer by decree. Progress occurs in a relatively unregulated environment involving the medical profession, researchers, pharmaceutical companies and other agents. But everything indicates that medical advances will speed up rather than slow down. My strong belief is that the EU will soon become a policy player, although officially the principle of national governments being responsible for policy-making will remain sacrosanct. All the actions taken by the Union currently (for example, the standardising of medical records, financial support of e-health initiatives including digitising X-rays, or supporting the development of EU centres of medical excellence) imply that there will be common standards and a coordinating body.

If we believe that the consumer should take action, this will be one of the main drivers. Different kinds of information systems must be designed for the consumer to be able to compare quality and outcomes. The Health Consumer Powerhouse introduced benchmarking processes for the European Union in 2005. There is a large potential for better healthcare within the current systems, provided we allow for partnerships

with the consumer. Such action supposes access to information. If we introduce market incentives within a wider framework, European healthcare could become a major growth industry.

11

Consumers and health information

Peter Pitts

Healthcare in the 21st century is a tale of two cities. The healthcare city on its exclusive hill provides miracles on a daily basis. We are living longer, healthier lives thanks in large measure to the miracles of biopharmaceuticals. If disease is the enemy, medication is our weapon. The sister city is the slum city of fear – fear of diminishing access, adverse events, the unknown and, most importantly, fear of responsibility.

Knowledge is power, but also a responsibility. Drugs have benefits, but they also have risks. In short, we do not live in a perfect world. This frightens many people when it comes to the miracles of modern medicine. According to recent polls, people are more distrustful of the pharmaceutical industry than before. Is this because more people are taking more medications? Is it because of drug safety issues such as the Vioxx recall and the lack of transparency of clinical trials? Is it because of the price/value debate? Of course, but those are manifestations of larger problems – such as confusion, frustration and fear.

Consumers have become a driving force in the health-care industry, demanding choice and access, spending their own money on self-care services, and making healthcare the number-one topic searched on the Internet. Patients, not physicians, are the fastest-growing readership segment of the major medical journals.

Welcome to 21st-century healthcare and the empowered consumer. Today, the ‘learned intermediary’ fears being replaced by the mass marketer, the patient is increasingly the purchaser (often a reluctant one), and physicians are becoming salesmen. Serious and life-threatening diseases have morphed from polio and diphtheria to cancer, Aids and Alzheimer’s disease. No wonder people are frightened – the entire healthcare paradigm has changed.

Change is frightening. Today, pharmaceutical companies are viewed as being in the business of making money rather than in the enterprise of discovery and development of life-saving therapies. Can savvy industry marketers help recapture the high ground by positioning the industry as made up of scientists rather than salesmen?

A good place to start would be to rethink consumer communications programmes, both direct-to-patient advertising and those with the broader goal of educating the industry’s various constituencies (ranging from patients to doctors, academics to legislators, policy wonks to pundits) on the role the industry plays in areas other than sales and marketing.

Educating the health consumer

A recent survey¹ in Europe asked people in Great Britain, the

Czech Republic, France, Germany, Italy, the Netherlands, Spain and Sweden what reforms would most likely increase their quality of care. In every nation, by a large margin, they answered 'giving patients more information about their illness'. Healthcare education is the consumer's Rosetta Stone, and public policy institutes, pharmaceutical firms, healthcare professionals, disease organisations and patient advocates, *along* with government, must be allied and aligned conduits.

There are four hard questions: (1) *what* should be said, (2) *to whom* should it be said, (3) *how* should it be said and (4) *who is responsible* for spreading the gospel of good health.

The '*what*' part is uncomfortably difficult, since many insurers and providers do not want their customers to know about safe and effective medicines because they do not want to pay for them. The '*to whom*' part is easy – health messages must be communicated broadly to consumers. The '*how*' part is more complicated.

Rudyard Kipling said, 'Words are the most powerful drug used by mankind.' This is particularly true when it comes to the issue of healthcare information to patients, because if government and industry do not know *what* can be said or *how* it can be said, then the public health is not being optimally served.

Europe has the opportunity to learn from America's many mistakes. Today the opportunity exists to devise a system wherein direct-to-patient information is designed in equal parts as savvy marketing strategy and powerful public health tool – because these are not mutually exclusive concepts. That being said, it is imperative to understand and accept that we are living in a post-Vioxx world where direct-to-patient information can no longer exclusively mean direct-to-consumer advertising

(DTCA). Today it must mean DTCC – direct-to-consumer communications.

The USA: reforms, research and regulations

Reforms in US direct-to-patient communications are being driven by the winds of the perfect storm – the nascent presidential election cycle, drug importation, Medicare modernisation and drug safety. A grand slam of highly charged issues made it not only possible but also predictable that the media and politicians would begin portraying Big Pharma as the new Big Tobacco.

Thus direct-to-consumer communications (in the USA most commonly meaning direct-to-consumer advertising) found themselves squarely in the bull's-eye of pundit satire and political outrage. It was in this context that trade organisation PhRMA launched its voluntary Guiding Principles for direct-to-consumer advertising.

Winston Churchill said, 'Americans always try to do the right thing – after they have tried everything else.' If the pharmaceutical industry wants to change its image on Capitol Hill and in homes nationwide then it is time to turn from pyrrhic victories to long-term strategies. In this respect, the new DTC guiding principles, although voluntary, are a very important step in the right direction.

In September 2003, I was Associate Commissioner at the Food and Drug Administration (FDA) and served as a panellist at a two-day public hearing on pharmaceutical direct-to-consumer advertising. Early in 2006, no longer a senior government official, I testified before my former colleagues on the

same subject. But what I heard was more important. According to research presented by academics from such places as Harvard Medical School and the Mayo Clinic, and by consumer advocates such as the National Consumers League, pharmaceutical direct-to-consumer advertising is, indeed, advancing America's health – most specifically by getting more people to visit their doctors.

Why? Because open and honest communication legitimises. More specifically, it helps to destigmatise certain diseases and encourages people to talk to their doctors about problems previously considered taboo – such as depression. Other research demonstrated little or no correlation between a brand's DTC spending and its cost. Brands that spend more heavily on DTC advertising do not necessarily cost more than their less advertised competition.

According to the Food and Drug Administration, between 3 and 5% of all doctor visits in the USA are scheduled specifically because a patient saw a pharmaceutical advertisement. We can debate whether or not 3–5% is a lot or a little, but it is a significant number.

Effects of advertising

According to FDA research, of patients who visited their doctors because of an ad, and who asked about that prescription drug by brand name, 87% actually had the condition the drug treats. But has the public health been served? Has DTC advanced America's health? The answer is a qualified 'yes.'

According to the same study, slightly less than half of doctors said that DTC-generated visits resulted in better discussions and made the patient more aware of treatments. And in 6%

of those advertising-generated visits, a previously undiagnosed condition was discovered. Earlier detection and appropriate treatment mean that more people will live longer, healthier, more productive lives without having to confront riskier, more costly medical interventions later.

Only 7% of doctors said they felt 'very pressured' to prescribe a particular advertised drug.

When the FDA panel probed into the question of 'pressure to prescribe', we found that the real pressure was *time* pressure. More patients are coming in armed with more questions.

Do physicians feel that direct-to-consumer advertising advances the public health? It depends. According to the FDA study, a majority of doctors feel that pharmaceutical advertising increases patient awareness and involvement, improves compliance and enhances the overall doctor–patient relationship.

Only 40%, however, said that DTC advertising has affected their patients and their practice either 'very' or 'somewhat' positively. Another 32% of the doctors surveyed believe that DTC ads have a 'somewhat' or 'very' negative impact, and the remaining 28% said it had no impact at all. Thus, there is definitely room for improvement.

Are patients informed?

How can pharmaceutical direct-to-patient advertising become a better public health instrument? According to the FDA's study, 65% of doctors feel that the DTC ads their patients see confuse them about the relative risks and benefits of prescription drugs.

That is a problem. It is, in fact, *the* big problem. In the agency's 1999 study, 56% of people who saw a pharmaceutical magazine ad said that they read the brief summary 'not at all' or 'a little'. (And it's a fair assumption that those who replied 'a little' were being polite.)

In the 2002 study that number jumped to 73% – a 17-point increase. During the same period, those saying they read 'almost all' or 'all' fell from 26% to 16%. In 1999 3% said they were not aware that there *even was* a brief summary. In 2002, this figure dropped a full decimal place to 0.3%. In other words, more people knew the brief summary was there, and fewer people were reading it. People's attitudes towards DTC ads changed during those same three years – for the worse.

In 1999, 70% of patients surveyed agreed either 'strongly' or 'somewhat' that 'Advertisements for prescription drugs give enough information for me to decide whether I should discuss the drug with my doctor'. In 2002 that number fell to 58%.

If information is power, then pharmaceutical advertising is not as empowering as it once was. Why? The answer is embarrassingly obvious. Risk information is hidden in plain view and benefits are communicated broadly. It is not a question of fault, but of fact. Risk information is neither designed nor delivered to be user-friendly. At present it is designed to be '*in compliance*'. How can DTC advertising change for the better?

Improving communications

Be it product advertising or disease awareness, the best and most expeditious solution is to apply sound *social* science to better communicating *medical* science.

Current information-to-patients policy, both in the USA and Europe, is not based on a scientific analysis of the target subject – the consumer. Hence a crucial question – where are the social science metrics driving government oversight of pharmaceutical information to patients?

As the FDA's Associate Commissioner, I toured the USA speaking to advocacy groups, physicians, consumers, pharmaceutical firms and communications professionals on how pharmaceutical communications could be made to more clearly and meaningfully communicate the risk/benefit equation of advertised drugs and raise the public's awareness of crucial health issues such as diabetes, hypertension and high cholesterol.

What I heard time and again was that the US government needed a solid benchmark study for sound policy decisions – a social-scientific protocol, a quantitative research project composed of structured, closed-ended questions and a sample size representative of the US population with regard to geography, race, gender, age and the treatment/disease of interest. A study that would provide insight into the most effective means to communicate risks in ways that are understood by the reader. A study that would provide a social-science-based regulatory framework, potential templates, metrics and, most importantly, add predictability to the government's review process. Today this process is under way – albeit slowly – in the USA. Europe should consider a similar study, because as any doctor will tell you, prescribing a solution without a proper diagnostic process is malpractice.

Reaffirm, redeploy and rethink

Today there is a new pharmaceutical Theory of Relativity: $R^3 = DTCC$. The three 'Rs' are derived from PhRMA's fifteen 'Guiding Principles', and the first 'R' is 'Reaffirm'. Eleven of the fifteen principles fall into this category. In essence, pharmaceutical companies will follow the rules and guidance set forth by the FDA – and every single new ad will be submitted for review.

The second 'R' is 'Redeploy'. Guiding Principle number 10 calls for the de facto banishment of reminder ads (which mention the product name, but not what the product does), resulting in the need to redeploy the dollars and tactics previously handled by these obnoxious little billboards. Other little things that will need to be redeployed, according to Guiding Principle number 13, are television ads that discuss lasting erections and satisfying experiences. Now they are limited to 'adult viewing hours'. Only in America would this be considered an 'advance.'

The third and most important 'R' is 'Rethink'. And it is here that the rubber really meets the road. This is the *R* that challenges the conventional wisdom of the pharmaceutical marketing mind. It is the *R* that demands a redefinition of long-term thinking from the end of the quarter to the end of the quarter-century.

Consider the third PhRMA Guiding Principle, 'DTC television and print advertising which is designed to market a prescription drug should also be designed to responsibly educate the consumer about the medicine and, where appropriate, the condition for which it may be prescribed'. Also number 14, 'Companies are encouraged to promote health and disease awareness as part of their DTC advertising'.

This is the operative phrase, 'promote health and disease awareness'.

While the passive-voice wording of these principles makes the overall effect more, well, passive, the main thrust of principles 3 and 14 is clear – less undisguised selling and more on-purpose education. It is an important first step in the campaign to reposition industry practitioners from being assailed as salesmen to a more preferred position as scientists. Educating about a disease means accepting the mantle of teacher. The teacher becomes the expert and the expert gets the business – but not in the same truncated time frame that hard-sell advertising produces.

'Promoting health and disease awareness' also means a fundamental shift in the marketing mix. Advertising is a wonderful brand builder but it's not nearly as potent a brain builder.

Direct-to-consumer communication means selling the brand as well as stimulating the brain. It means new strategies and tactics. The time is gone when a pharmaceutical CEO can speak about 'responsible promotion' while turning a blind eye to the actual tactics being used on the air and in the doctor's office to meet aggressive quotas and keep Wall Street happy.

It is about saving lives and saving our healthcare system. It is about improving disease awareness and defeating patient non-compliance – estimated to cost the US healthcare system billions of dollars a year in increased emergency room visits, unnecessary surgeries, expensive hospital stays and lost productivity.

Understandable and accessible information that employs leveraged learning strategies and incorporates both brain and branded messages will also help address the global crisis of

embarrassingly low health literacy. Successful DTCC requires a *reaffirmation of responsibility*, a *redeployment and reassessment of resources*, and the toughest *R* of all, the ability and willingness to *rethink* the roles of the many tools in the pharmaceutical marketing armamentarium. $R^3 = DTCC$.

Notes

Chapter 2 Getting the politics out of healthcare

- 1 Interestingly, since this talk was given, the Supreme Court of Canada (in the Chaoulli case) described the Canadian healthcare system in almost exactly these terms.

Chapter 10 The health consumer vision

- 1 *Impatient for Change*, Stockholm Network/Populus (2004).

Chapter 11 Consumers and health information

- 1 *Impatient for Change*, Stockholm Network/Populus (2004).

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Coincidence or Crisis?

Prescription medicine counterfeiting

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The business of creating, distributing and selling counterfeit pharmaceutical products is an unregulated, criminal and growing part of the global economy. Evidence of this criminal activity is mounting: according to a 1997 World Health Organization report, 10%–20% of drugs tested in developing countries are either counterfeit or have not been handled according to the manufacturers' specifications.

In Europe, profiteers masquerading as pharmacists are selling a nightmarish cornucopia of unsafe, unregulated, mislabelled, repackaged and co-mingled drugs to unsuspecting consumers.

Coincidence or Crisis? brings together some of the world's leading experts to discuss the growth of counterfeit pharmaceuticals. It provides a comprehensive analysis of the core issues, while delimiting key strategies to tackle the problem.

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