

Testimony of
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Hearing on
Drug Importation: Would the Price Be Right?
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Executive Summary:

There is only one thing which really matters when examining health policy: the patient. Whatever reforms might be proposed, the deciding factor must be the impact on the patient.

European patients suffer directly (and avoidably) as a result of two inter-related problems: price controls and parallel trade. Importation will weaken, if not destroy, the US's global dominance in developing new biotech drugs because, as well as importing foreign drugs, importation will also import the foreign price controls which falsely lower prices and, in so doing, deny patients access to new medicines and drive away R&D.

Because each of the 25 Member States has its own regulatory framework and approach to pharmaceutical pricing, what emerges is a price competition not between pharmaceutical manufacturers but between state-determined price controls. And so arbitrageurs import drugs from and make easy profits. Those profits do not contribute to R&D or to the broader health care economy. They do not widen access. They simply make profits on the back of foreign governments' price controls.

In 1990, major European research-based companies spent 73% of their global R&D expenditure in the EU, but only 59% in 1999. Between 1993 and 1997, 81 unique new drugs were launched in Europe, compared to 48 in the U.S.; but from 1998 to 2002, the European number had declined to 44 while the U.S. number rose to 85. Europe's share of world pharmaceutical research had fallen from 32 per cent to 22 per cent.

Price control has limited the profitability of European pharmaceutical companies in their home markets, and has crippled their willingness and ability to spend on development of new products.

Those who favour importation into the US are arguing for the importation of all these problems.

An array of cost containment measures are limiting pharmaceutical spending within EU Member States. Only 5 percent of UK patients with a prostate cancer are treated by an oncologist. 40 percent of all breast-cancer patients die in Germany - compared to 26 percent in the United States - due partly to a lack of use of innovative medicines. And with cardio-vascular disease, 83 percent of Italians, 77 percent of Brits and 74 percent of Germans receive suboptimal treatment, compared to only 44 percent of Americans.

This is not by accident. It is by design, and is the inevitable consequences of the price controls which come alongside parallel trade. American concern with European "free riding" on investment in R&D is understandable, and justified. But the correct response is for Europe to get its act together, not for the US to adopt the same mistaken policies which have caused the problem in the first place.

Mr. Chairman, and Members of the Committee:

Testimony:

I am honoured to be invited to testify before you this morning to give you a European perspective on this most critical of healthcare issues.

For your information, my background is in policy making for the Labour Party in Great Britain. After a spell working for a senior Labour Member of Parliament in the late 1980s, I then became Research Director of the Fabian Society, the oldest think tank in the world and the Labour Party's 'in house' policy proposing vehicle. My time there coincided with Tony Blair's election as party leader, and I remain proud today to describe myself as a 'Blairite'.

After leaving the Fabian Society I became Head of Research at an independent think tank, the Social Market Foundation. I then switched to journalism, writing on public policy issues. Today, I combine think tank work with journalism.

My brief at the Fabian Society was to examine how Labour, then a party which had lost four general elections in a row, could transform itself into a modern party of government. It soon became clear to me that the issue of healthcare was emblematic both of the party's failure to adapt to the modern world and how it could indeed transform itself. Our attitude to the structure and funding of health care was fundamental. So over time, through force of circumstance, I came to specialise in health care policy. Now my work brings that specialisation to a European audience.

In my role as Director of the Health Unit at the Centre for the New Europe, a free market think tank in Brussels, I study health systems across the European Union (and beyond). All have their own problems; some are unique, most are shared.

When I analyse these problems, I come at the issues from a left-of-centre (or, in US parlance, liberal) perspective. That means that in my view there is only one thing which really matters when examining health policy: the patient. Whatever reforms might be proposed, the deciding factor must be the impact on the patient. Anything which gives the patient better access to good healthcare should be considered; anything which detracts from that should be resisted. I thus have an open mind about mechanisms and machinery.

In that context, it is clear to me – the evidence is unarguable – that European patients suffer directly (and avoidably) as a result of two inter-related problems: price controls and parallel trade. There are, I venture to suggest, many ideas which the US might consider importing from Europe. What puzzles me is why, despite the experience of European patients, the US should be considering importing one of the most damaging and dangerous aspects of our health care arrangements.

On one level it is obvious. The response to relatively high drug prices in the US has been to look at importation from Canada and Europe. Why pay more, after all, when something is available cheaper elsewhere? But the European experience shows that the logic is deeply flawed, and the consequences deeply damaging.

First, price discrimination (when a good is sold at different non-marginal cost related prices) has a rational economic purpose which can be entirely justified on welfare

grounds. It enables companies to offer products which would otherwise be unavailable. If price discrimination is not possible then, by definition, only one price can be set. That price will almost always be higher than many consumers can or will pay. When the good in question is a medicine, and the aim is to widen access, that matters.

As Julian Morris puts it (ADPIC et Services Médicaux : Repenser le Débat, Centre for the New Europe, 2001): “Price discrimination thus benefits all. Poorer people less able or unable to pay the normal, uniform profit maximising price gain access they otherwise would not. Today’s medicines, for example, can be made available more cheaply. Producers reap greater profits, increasing incentives for research to develop tomorrow’s medicines more quickly. And a portion of these additional profits comes from the better off who have the most obvious revealed desire to purchase innovations (as indicated by their willingness to pay) and who tend (sometimes, but not always), to have altruistic feelings towards the poor and less privileged... The ability to practice discriminatory pricing also depends on lack of arbitrage or leakage between segments. The firm can only charge the different prices in the segments if it is not possible for a third party to come along and buy cheap in the one segment, and sell dear in another (‘sell dear’ certainly, but at a lower price than the existing firm is currently charging).”

That is undermined by parallel trade. Importation will weaken, if not destroy, the US’s global dominance in developing new biotech drugs. It will do that because, as well as importing foreign drugs, importation will also import the foreign price controls which falsely lower prices and, in so doing, deny patients access to new medicines and drive away R&D.

This is not just theory; it is the current experience of European patients.

Article 28 of the Treaty of Rome, as strengthened by the Single European Act, creates a single market within the European Union. With a few restrictions in the interests of public health and public morals, whatever may be freely bought in any one member state must be freely allowed into any other.

Because each of the 25 Member States has its own regulatory framework and approach to pharmaceutical pricing, what emerges is a price competition not between pharmaceutical manufacturers but between state-determined price controls. Thus in a country such as Greece, which imposes severe restrictions, drugs can cost less than in, for example, the UK. And so arbitrageurs import drugs from Greece and make easy profits. Those profits remain in their pockets. They do not contribute to R&D. They do not contribute to the broader health care economy. They do not widen access. They simply make profits on the back of foreign governments’ price controls. And, as a result, the EU-based pharmaceutical industry and R&D research capacity is fast disappearing. Incentives are significantly reduced for large biotech and pharmaceutical companies to engage in research, just as they are for venture capitalists to invest their funds in startup biotech firms. Healthcare as a whole suffers because the overall cost of care rises when the introduction of innovative treatments for illnesses is slowed. The quality of care decreases as the supply of innovative medicines falls short of demand.

By the end of 2001, the parallel trade in pharmaceutical products reached \$3.3 billion in Europe, and is set to reach \$7.4 billion by 2006. In Germany, the biggest pharmaceutical market in the European Union by volume and value (and the third largest market worldwide) – and thus a key target for parallel traders - parallel trade has grown exponentially since 2000 following the enactment of a law requiring pharmacists to replace brand names with imported drugs when the latter are at least 10% cheaper. Between 1998 and 2001, parallel trade more than trebled, from 260 to more than 800 million euros. The market share of imported drugs increased from 1.8% in 1998 to 5.8% in January 2002.

As in all other countries, the National Health Service in the UK is under severe cost constraints. While there is no control of prices in Britain, purchasers do of course take advantage of the immediate cost savings from importing pharmaceutical products from parts of the European Union where price control makes them substantially cheaper.

Licences granted for parallel imports went from 426 in 1995 to 1,363 in 2000 and applications have continued growing since then. By 2002, Britain had the third highest penetration of imports (11 per cent) after the Netherlands and Denmark. Parallel trade volume increased by 38 per cent in 2001 and a further 20 per cent to the end of 2002. The Association of British Pharmaceutical Industries puts the loss of income at £1 billion per year. As Britain remains outside of the Euro, there are substantial profits to be made from exchange rate differentials. Other factors include the volume of and ease of becoming an importer to the UK; the lack of patient push-back and their compliance with the system. The lack of appropriate regulatory involvement in the monitoring of imports and importers is a factor. So is the vertical integration of wholesalers and pharmacists in the UK.

According to the Consumers' Association, 90 per cent of British pharmacists source products through parallel trade. This saves the National Health Service approximately £60 million a year or some 0.5 per cent of the country's medicines budget. Today, however, Britain is a major destination for imports in Europe with an estimated drug expenditure of £5 billion in 2000. Nevertheless, the traders involved cream off £350 million a year.

According to Pfizer, 60 per cent of British sales of Lipitor – which is used for the treatment of high cholesterol – are supplied by parallel importation. By 2001, up to one eighth of all National Health Service medicines were already dispensed using parallel imports. And today, according to the Association of British Pharmaceutical Industries, one in five branded prescriptions are now filled by a parallel traded product. One source indicates that by late 2004, 20 per cent of all British prescriptions would be imports.

In this way, the adverse effects of price control are spread by free trade from one market to another. If this were the case with textiles or home electronics equipment, there would be no reasonable grounds for worry. Here, trade enhances social welfare through superior efficiency of lower real costs. In the case of pharmaceuticals, however, lower prices in the exporting countries simply reflect greater regulatory leverage. Prices are lower in countries like Spain than in Britain not because costs are

lower or competition is greater, but simply because the Spanish Government has decreed them to be lower.

In May 2004, ten new member states joined the European Union. Those from the former Soviet bloc – for example, the Czech Republic, Slovakia and Poland – have significant pharmaceutical sectors and significantly lower prices of imported products. The accession treaties specify that for the new member states, and in particular the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia, that parallel imports shall be prevented until the patent or supplementary protection of the medicinal product concerned expires in these member states. But this is a temporary restriction. Given the combination of a single market and national price regulation, the only direction for the parallel trade is upwards.

So far, pharmaceutical companies have continued to invest in research and development of new products despite price regulation in even the majority of their markets. It has only been necessary for them to be able to set prices in some markets for them to be able to recover their whole costs of production. We are now entering a world in which whatever country has the most restricting price control scheme will become the largest exporter of pharmaceutical products; and the pharmaceutical companies will find themselves pressured into marginal pricing in all their markets.

From 1992 to 2001 over 400,000 new jobs were created in the US in the biotech and related industries. These have been made possible by investment in R&D from pharmaceutical companies and new biotech start-ups. A mere 0.0002 percent of potential new drugs make it to the market; most such biotech firms fail. But the investment is made because the patent system allows the eventual price to cover this research. Importing price controls from the EU and Canada threatens all this by reducing the returns on investment to a level set by foreign drugs regulators with no concern for the complex R&D economy. Investors will simply go elsewhere, and the research will not happen.

Look at Europe. Total pharmaceutical production in Europe in 2001 amounted to €130 billion (\$140 billion) and € 138 billion (\$150 billion) in 2002. The industry employed approximately 560,000 people in 2002 of which 82,500 were in research and development. The European share of the world pharmaceutical market has declined from 32% to 22% over the past decade; the US share increased from 31 to 43%. Similarly, in 1990 major European research-based companies spent 73% of their global R&D expenditure in the EU, but only 59% in 1999. On average, European countries spend 8% of GDP on healthcare compared to about 14% in the USA. According to Gilbert & Rosenberg (In Vivo, March 2004), between 1993 and 1997, 81 unique new drugs were launched in Europe, compared to 48 in the U.S.; but from 1998 to 2002, the European number had declined to 44 while the U.S. number rose to 85.

This has caused job losses. The large Swiss company, Novartis, recently moved its research facilities to the United States. From 1990 to 2001 the number of high value-added employees in Germany's drug industry fell by 36 percent (while those in the United States increased by 52 percent).

This matters not just because of its impact on the European Union economy, but because of a direct effect on the quality of care available to European patients.

Every member state of the EU has some kind of welfare safety net for its citizens. In all member states, perhaps the most important part of this safety net is the health care system, in which medical treatment is made available to citizens without regard to ability to pay. The financing of health care differs across the member states. In Britain, the National Health Service aims to provide a universal system of care free at the point of use. In most other member states, it is provided more or less by the independent sector, with means tested subsidies or reimbursements given to individual patients by the State.

However financed, the burden of public health care has pressed increasingly heavy on European tax payers for at least the past generation. Because people are living longer, they are dying of illnesses for which there is no cure, and for which palliative treatments are complex and expensive. Even otherwise, people are now expecting more of health services than ever before. Unlike their ancestors, people now are less willing to live with chronic pain and disability.

Because it is the largest and most elaborate scheme of provision in Europe, these effects can be seen most clearly in the budgets of the National Health Service. Government spending on the system has increased by 50 per cent in money terms since 1997. The 2002 budget outlined plan to increase spending by a further £18 billion over the next three years. Despite this, complaints continue of under-funding. Almost as clearly, these effects can be seen in every European health service. In France, for example, the health service is calculated to have been €14 billion per year in deficit by the end of 2004. As of April 2004, the Slovak health service was running a deficit of 9 billion Crowns – or €200 million.

There are numerous ways of dealing with this inflation of health care costs. One of the easiest and most obvious is to cut the cost of the drugs bill. This is not the most important single cost, but it is a large cost. Pharmaceutical products, for example, account for 12 per cent of the National Health Service budget, and the proportion is somewhat higher in most of continental Europe. Any reduction is likely to be welcomed by the politicians and managers who are trying hard to squeeze as much as they can out of increasingly inelastic budgets.

For this reason, every member state of the European Union has in place some scheme to regulate the price of pharmaceutical products. In every member state, the state is the largest singly buyer – directly or indirectly – of pharmaceutical products; and so the health authorities can use their monopsonistic power to negotiate lower prices than would otherwise obtain. These prices are then enforced generally through laws that prohibit the charging of different prices for the same product. To give a detailed review of these schemes across each Member State is not possible in so short a paper as this. Indeed, as the schemes generally lack transparency, even an overview would require a book in itself. In brief, however, the regulatory schemes can be set within two categories.

First, there are those countries where prices are set largely by reference to marginal cost of production. These countries are: Austria, Belgium, Denmark, Finland, France,

Luxemburg, Spain, Sweden, and – in part – Germany. Here, prices are supposed to reflect production costs and allow for a certain margin of profit. However, negotiations between pharmaceutical companies and the health authorities often lead to prices based on criteria hard for outsiders to comprehend.

Second, there are those countries where prices are set largely by reference to the price of the same product in neighbouring countries. These countries are: Greece, Holland, Ireland, Portugal, and – in part – Italy. In most cases, average prices are based on controlled prices, and so there may be a further downward pressure.

The exception to this rule is Britain, where the National Health Service uses its immense buying power to get lower prices, but allows an average profit of 21 per cent to its pharmaceutical suppliers, and is willing to allow the margins of specific products to vary significantly.

In most of its forms, price control leads to consequences that can be reasonably comprehended – and are immediately bad. If, for example, a government wants to fix the price of some product below its immediate costs of production, there will be an increase in demand and a fall in supply, leading to shortages in the market. The effects of price control are different where pharmaceutical products are concerned. In no European country are prices set below marginal cost of production – and it would be hard for this to happen, bearing in mind in most cases the very low marginal costs of production. Instead, profit margins are squeezed.

But there are (following the idea of the great French economist Frédéric Bastiat's essay of 1850, "What is Seen and What is not Seen"), two consequences of pharmaceutical price controls; one 'seen', the other 'unseen' or unintended. It is the latter which should cause concern.

The 'seen consequence' is to hold down medical costs, allowing wider access at any one time to treatment than would otherwise be the case.

Its 'unseen consequences' however are to diminish the range of treatments available in the long term, and to increase medical costs. Price control will in the long term reduce the number of new products introduced to the market. And it may actually increase pressure on health budgets. Money spent on pharmaceutical products is, of course, a cost. But it is also a cost saving, taking into account often larger amounts of money that would otherwise need to be spent on less effective forms of treatments. In this respect, any budget savings that damage the ability of the pharmaceutical companies to continue developing new products are not savings at all, given any other view than that of short run neoclassical market analysis.

And we can see clear evidence from Europe that price control is reducing the rate of innovation. Until the 1980s, continental Europe had a dynamic and innovative pharmaceutical sector. Germany, in particular, had long had a distinguished record in pharmaceutical innovation – from morphine and heroin and aspirin in the 19th century, to Cipro and Baycol in the 20th. With the exception of Britain, all these sectors are in decline. In 1990, pharmaceutical companies spent \$7.2 billion on research in Europe, and \$4.9 billion in the United States. By 2000, spending in Europe had risen to \$16.9 billion, but in the United States to \$23.7 billion.

Granted, this does mean an increase in European budgets. But these are exceptional times for pharmaceutical research. During the past generation, research and development budgets in the pharmaceutical sector have been rising at 7.1 per cent a year. Between 1996 and 2001, the pharmaceutical industry as a whole spent \$130 billion on research and development – more than in the whole of the previous 25 years. Yet while the pharmaceutical companies in Europe doubled research during the 1990s, they quintupled it in America. Put another way, Europe's share of world pharmaceutical research had fallen from 32 per cent to 22 per cent.

The results are easy to see. In 1988, three of the best selling new pharmaceutical products in the world had been developed in Britain. By 2000, there were none from Britain – and Britain still has a viable pharmaceutical sector. In Germany, investment in pharmaceutical research has been declining. Germany had 16 per cent of the world's new drug patents in the years 1980 to 1985, but that share dropped to 8 per cent in the years 1986 to 1990. In France, there is almost no innovation – yet France in 1970 was third in the world in terms of new patents for pharmaceutical products.

Price control has limited the profitability of European pharmaceutical companies in their home markets, and has crippled their willingness and ability to spend on development of new products.

Of course, it may be argued, the effect of price control need not be so great. So long as other markets in the world remain uncontrolled, research and development will continue there.

Perhaps the continental Europeans are enjoying continued medical progress at the expense of British and America health care schemes. Perhaps this is unfair. But unfairness is no argument in itself against continuing with a policy that reduces medical costs in one country at the expense of another. Complaints are only to be taken seriously when it can be shown that control has put brakes on the rate of pharmaceutical innovation.

There are two replies to this argument.

First, price control does apply such brakes. Medicine is not like mathematics or pure physics, where speculation is wholly abstract, and separate from any cultural bias. Medical research may be a science, but the objects of research are determined by cultural bias. For example, it was found in the 1960s that the same constellation of symptoms were routinely diagnosed in America as emphysema and in Britain as chronic bronchitis. In Britain and France, there were apparent differences in the incidence of schizophrenia. On examination, it was found that French doctors were much less willing to make the diagnosis.

According to this view, every developed nation has something unique and important to add in the field of medical research. If Germany and France now count for little in this field, the whole world is poorer for the decline. Perhaps only in Germany could aspirin have been developed, just as only in Britain could Penicillin. Perhaps the decline of the German pharmaceutical sector is robbing humanity of something equally important.

Second, the more often countries able to bear the full cost price of pharmaceutical products push prices towards marginal cost, the less able the pharmaceutical companies are to supply products at slightly above marginal cost to poorer countries. Every time a European government forces down the price of some pharmaceutical product, it is to some degree making that product less available to patients in the third world.

The pharmaceutical industry has come under considerable fire in recent years regarding the supply of medicines to lesser-developed countries. However, by imposing price controls, it is the European governments who are imposing costs on the developing world. This policy is most probably counter-productive, since the costs to European governments in terms of aid and trade with developing countries are likely to be much higher than the short-term savings from price controls. This is clearly a complex and controversial debate, which lies outside the remit of this paper, but perhaps needs to be explored further elsewhere.

In a world of increasingly open trade, the effects of price control are no longer confined to the market where they are applied. They now extend via parallel trade into markets where no price control exists. Those who favour importation into the US are arguing for the importation of all these problems.

(Given the focus of today's session, I have ignored the patient safety issue, which is no less worrying.)

To start at the beginning: governments which pay for pharmaceuticals involve themselves, as night follows day, in both pricing and availability. Although the EU-wide drug approval process is capable of speedy decision making, at Member State level speed disappears as individual health and finance ministries create a series of differing barriers against the introduction of new drugs. In countries such as Belgium France and Greece, for example, with heavy regulation, new drugs take an average of nine months after EU approval to reach patients.

That is the average. Taxol, a medication to treat advanced breast cancer and refractory ovarian cancer, was approved in 1995, but did not reach British cancer patients until 2000. It is no surprise that the UK has lower breast cancer survival rates than the US and much of Europe.

In 1995, new EU-wide procedures were introduced to do two things: to strengthen the role of 'mutual recognition', by which companies with permission to market their drug in one country could apply for this to be acknowledged across the EU; and to introduce a complementary, formal structure under which a drug could be approved centrally with so-called 'Community Marketing Authorisation' for use across the EU by the European Medicines Evaluation Agency. According to the EU directives, granting of mutual recognition status should take no longer than 90 days beyond the date of application, and pricing and re-imburement no longer than a further 180 days.

In a report published in 2000, the consultancy Europe Economics examined the three methods – one national and two EU-wide - of approval. It found astonishing variations within an overall picture of heavy delays. Among those drugs sent for

approval at national level, patients in the countries with the longest delays finally got access to new drugs four years after patients in the quickest countries. The worst countries were France, Greece and Portugal (an average delay of over two and a half years), with Belgium, Germany and Austria not far behind.

Europe Economics then looked at all 24 of the medicines sent for the new system of central approval between 1995 and 1997. Delays between approval being granted and their appearance at pharmacies were longest in Portugal, Italy and Spain, with bad delays also in Greece, Belgium, France and Ireland. 20 of the 24 drugs were not on the market in Portugal by the time the survey stopped at the end of 1998. Even in Germany, with a relatively good record, 6 of the 24 were still unavailable. Belgium, Greece and Portugal were the countries with the worst delays in patient access for those medicines approved under the new mutual recognition procedure. Europe Economics only examined seven countries' records here, but in every one of them the delay far outstripped the 90 days permitted in the regulation.

Overall, the report found that EU patients faced an average delay of over two years before gaining access to a new drug after licensing by their own Member State, whilst patients in the most dilatory Member State had to wait four years.

The leading cause of this crisis is hardly a revelation: cost containment and price controls. An array of highly pointed and increasingly effective cost containment measures are becoming increasingly successful at limiting pharmaceutical spending within EU Member States. Take cardiovascular medicine, where so high are the hurdles for reimbursement (in Italy and Belgium the threshold is a cholesterol level of about 290, plus proof of family history, even though established medical opinion holds that 190 is the appropriate level) that the most innovative and effective lipid-lowering therapy is only available to heart attack sufferers. Even in countries which once had a relatively good story to tell, cost-containment is now beginning to undermine patient access, as the British government's establishment of the National Institute for Clinical Excellence shows.

The most extensive study of these delays has been undertaken by Prof Oliver Schoffski, at the University of Erlangen-Nuremberg. In a report published in January 2003 ("Diffusion of Medicines in Europe", which can be downloaded from his website at the University of Erlangen-Nuremberg: <http://www.gm.wiso.uni-erlangen.de>) he examined the treatment of 20 illnesses across Europe, incorporating nearly 200 studies of how people were treated. He concludes that although effective medicines exist and are available in principle for all eligible patients throughout Europe, not everyone receives adequate treatment; in some cases patients are not treated at all; in other cases they only receive outdated medicines (with lower effectiveness or with more severe side-effects), while prescribed dosages can also be too low to have an effect.

Data collected by Prof. Schoffski show, for example, that in Germany one million people suffer from migraine unnecessarily. In France, 9 in 10 patients with acute asthma do not receive adequate care.

Take diabetes. Diabetes is one of the most common diseases of western civilisation; it affects more than 18 million people in the EU. If diabetes is treated in the proper way,

other serious and expensive illnesses like strokes, heart attacks, blindness or amputations can be avoided, or at least delayed for a long time. There is a fundamental problem of lack of proper diagnosis: in France about 60% of patients are not monitored satisfactorily. But even when patients are diagnosed, they do not receive proper medication. In Germany 30% of at least four million diabetes patients receive no medicine at all as a result of cost cutting. Yet with proper treatment a huge amount of unnecessary costs could be avoided: the 6000 annual German cases of blindness, the 8000 new dialysis patients, the 27,000 heart attacks, the 28,000 amputations and 44,000 strokes, all of which are the result of inadequate diabetes treatment.

Only 5 percent of UK patients with prostate cancer are treated by an oncologist. 40 percent of all breast-cancer patients die in Germany - compared to 26 percent in the United States - due partly to a lack of use of innovative medicines. And with cardiovascular disease, 83 percent of Italians, 77 percent of Brits and 74 percent of Germans receive suboptimal treatment, compared to only 44 percent of Americans.

This is not by accident. It is by design, and is the inevitable consequences of the price controls which come alongside parallel trade. The UK's National Institute of Clinical Excellence, for example, exists specifically to reduce choice. NICE was set up in April 1999 with one of the most misleading launch promises in history: spreading excellence throughout the National Health Service and ensuring that all patients received access to the 'best' treatments available.

But there is a golden rule in public policy: the name of a body is, almost always, the exact opposite of its real effect on the world. Its real effect – one might say its real purpose - has been rather different: to restrict the variety of treatments available to patients. In reality, NICE was set up to provide an independent, expert justification for the rationing which has always been a fundamental and necessary part of the NHS' modus operandi. Rather than NICE, it might best be described as NASTY: Not Available, So Treat Yourself.

The German Centre for Quality Medicine, similarly, is supposed be able to issue guidance to doctors across all of Germany, ensuring up to date knowledge of the latest research and that the most effective medicines are used on patients. It sounds wonderful in theory. But the practice, as NICE shows, is rather different. In reality these decisions are about not widening the range of treatments but narrowing them; not increasing the options but restricting them. They are, in short, designed to ration health care, and to do so in the most misleading manner possible – on the pretext of rationality.

The rationale behind such a policy is clear. The healthier we get, the more we spend on healthcare. Demand for healthcare seems to rise inexorably, driven by a cocktail of demographics, new technologies and expectations. Across the globe, those responsible for the delivery of healthcare strive to find ways to limit the rate of growth in spending. These have taken a variety of forms, from HMOs in the US to restructuring of some social insurance models in Europe. Whatever other merits they have, they all have this same overriding concern as a driving force.

As one of its main decision-making tools, NICE employs economic evaluation, a method which is becoming increasingly required by healthcare decision-makers. Economic evaluation involves the comparison of the costs and consequences of alternative treatments for a given condition. It is promoted as a rational, scientific means of allocating resources and containing costs. In reality, it is a spurious justification for rationing drugs which would have a significant impact on spending.

The crucial words are ‘clinical excellence’, and how they are defined. The unavoidable truth is that such decisions cannot be value-free. The decision making process – which drugs to allow, and which to bar - represent a set of value judgements which are hidden from view and may not reflect the values that the general public would like to use in the allocation of healthcare resources. Such decisions go to the heart of economics – and of politics. Indeed, the cynic’s view of NICE is the only plausible view: the very purpose of basing rationing decisions on the outcomes of such evaluation is to provide a supposedly objective alibi behind which intensely unpopular political decisions –rationing healthcare – can be hidden. Subjective choices about which treatments to deny, and to which groups of patients, are thus disguised as objective decision-making, and given entirely spurious credibility, when in reality they are no more objective than any other political decision.

Even the most cursory look at NICE’s methodology and purpose shows precisely how it ends up denying treatments to patients which they would otherwise have had. The list of drugs which NICE now refuses to sanction is almost endless:

In 2002, NICE said that irinotecan and oxaliplatin should not be used as first line treatment for advanced colorectal cancer, even though they are licensed for this in the UK with an established drug 5FU. They added that a third drug, raltitrexed, should only be used in clinical trials. The real reason? The newer drugs cost £1,200 per patient a year, compared to the £70 of more traditional treatments.

In the same year, 2002, NICE said that there was ‘insufficient evidence’ to recommend the use of a new cancer medicine which has clearly proved its efficacy in the treatment of patients in two of the three phases of chronic myeloid leukaemia. The medicine has been licensed for all three phases in 65 countries around the world – but not, thanks to NICE, in the UK.

Relenza for influenza, beta interferon for multiple sclerosis, herceptin for breast cancer: on and on the list goes, all on the basis of supposed ‘clinical excellence’ – and all, in reality, based on a desire to save money.

Prof Schoffski describes “a huge difference between a possible optimal treatment and the treatment delivered to the patient”. Current drug budget management in many EU countries (i.e. drug pricing policy, inadequate government planning and cost-containment measures) leads to sub-optimal medical treatment of the European population for many pathologies.

There were, he found, five strongly interrelated factors influencing the diffusion of effective medicines in national health care systems: patient related, health care professionals related, industry related, system related (long term) and policy related (short term) factors – which he concluded are the most important.

American concern with European “free riding” on investment in R&D is understandable, and justified. European governments are, in effect, shifting the cost burden of research from Europe to the US. But the correct response is for Europe to get its act together, not for the US to adopt the same mistaken policies which have caused the problem in the first place. By adopting drug-importation measures, the US will simply be importing the same problems arising out of price controls and leading to diminished incentives for innovation. The price differences might fall, but so too will everything else – critically, health care.

There is, unfortunately, no such thing as a free lunch. You cannot get something for nothing. Importation might look like a panacea but it is no such thing. It involves the importation of the price controls which have wreaked havoc with European patients’ health care and the European pharmaceutical industry. The argument is made that this is an issue of free trade. It is not. Allowing such imports will not, as one proponent put it, “allow American consumers, particularly seniors, to benefit from worldwide price competition”. Far from “inserting competition and the free market into the pricing of medication.”, as another advocate put it, there is no competition. There is simply pricing by governmental diktat, with all the deleterious consequences outlined above.

One congressman - a free market conservative – argued that importation would force drug makers “to present the price-setting countries with an ultimatum: Either liberalize your market or we will leave. It’s hard to imagine that countries in this situation will deny their citizens access to life-saving drugs.”. Clearly, he has never studied healthcare in Europe, where denying access to life-saving drugs is almost a matter of policy.

The fate of the pharmaceutical industry would be irrelevant to my concerns but for one thing. It is R&D which saves lives, and innovation which transforms the quality of life of patients across the globe. If the pharmaceutical industry is unable to undertake such research, we all suffer. It is precisely because the patient should come first that the sophistic and superficially appealing arguments in favour of importation should be resisted. Unless, that is, the US wishes to turn itself into Europe, and deny its patients.